US011123551B2

United States Patent

Hoffman et al.

(10) Patent No.: US 11,123,551 B2

(45) Date of Patent: Sep. 21, 2021

(54) **COCHLEAR IMPLANTS INCLUDING ELECTRODE ARRAYS AND METHODS OF MAKING THE SAME**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 156 days.

(21) Appl. No.: **16/463,957**

(22) PCT Filed: **Dec. 1, 2017**

(86) PCT No.: **PCT/US2017/064231**

§ 371 (c)(1),
(2) Date: **May 24, 2019**

(87) PCT Pub. No.: **WO2018/102695**

PCT Pub. Date: **Jun. 7, 2018**

(65) **Prior Publication Data**

US 2020/0384262 A1 Dec. 10, 2020

Related U.S. Application Data

(60) Provisional application No. 62/428,668, filed on Dec. 1, 2016.

(51) **Int. Cl.**

A61N 1/05	(2006.01)
A61N 1/36	(2006.01)
A61N 1/375	(2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/0541*** (2013.01); ***A61N 1/36038*** (2017.08); ***A61N 1/3752*** (2013.01)

(58) **Field of Classification Search**

CPC A61N 1/0541; A61N 1/36038; A61N 1/3752

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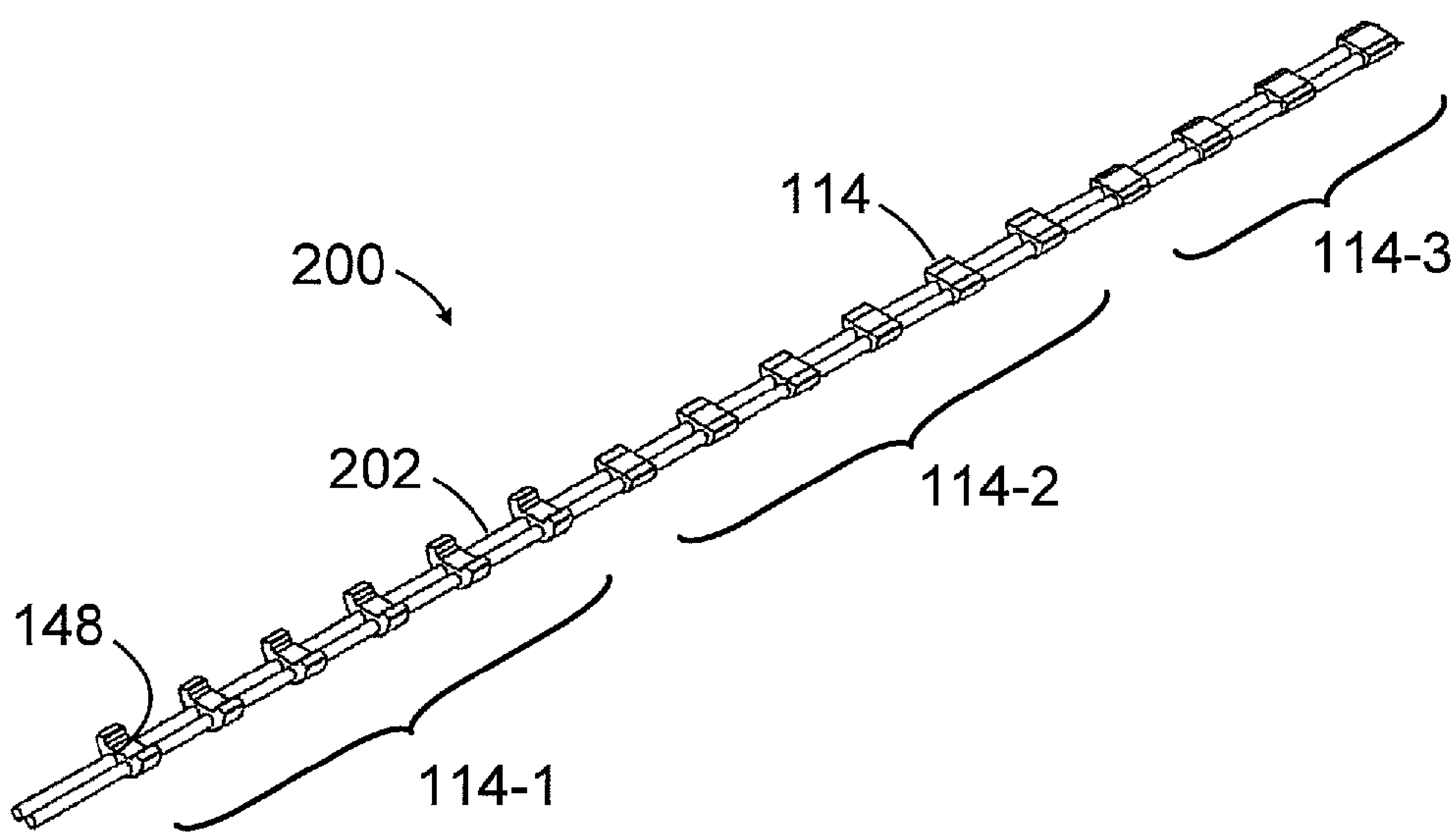
Primary Examiner — Mallika D Fairchild
Assistant Examiner — Minh Duc G Pham
(74) *Attorney, Agent, or Firm* — Henricks Slavin LLP

(57) **ABSTRACT**

A method of forming a cochlear implant electrode array includes positioning contact array assembly, which includes at least one carrier and a plurality of contacts on the at least one carrier, in a mold, removing at least a portion of the at least one carrier from the mold without removing that plurality of contacts from the mold, and introducing resilient material into the mold after the at least a portion of the at least one carrier has been removed to form a flexible body.

21 Claims, 26 Drawing Sheets



(58) **Field of Classification Search**
USPC 607/57
See application file for complete search history.

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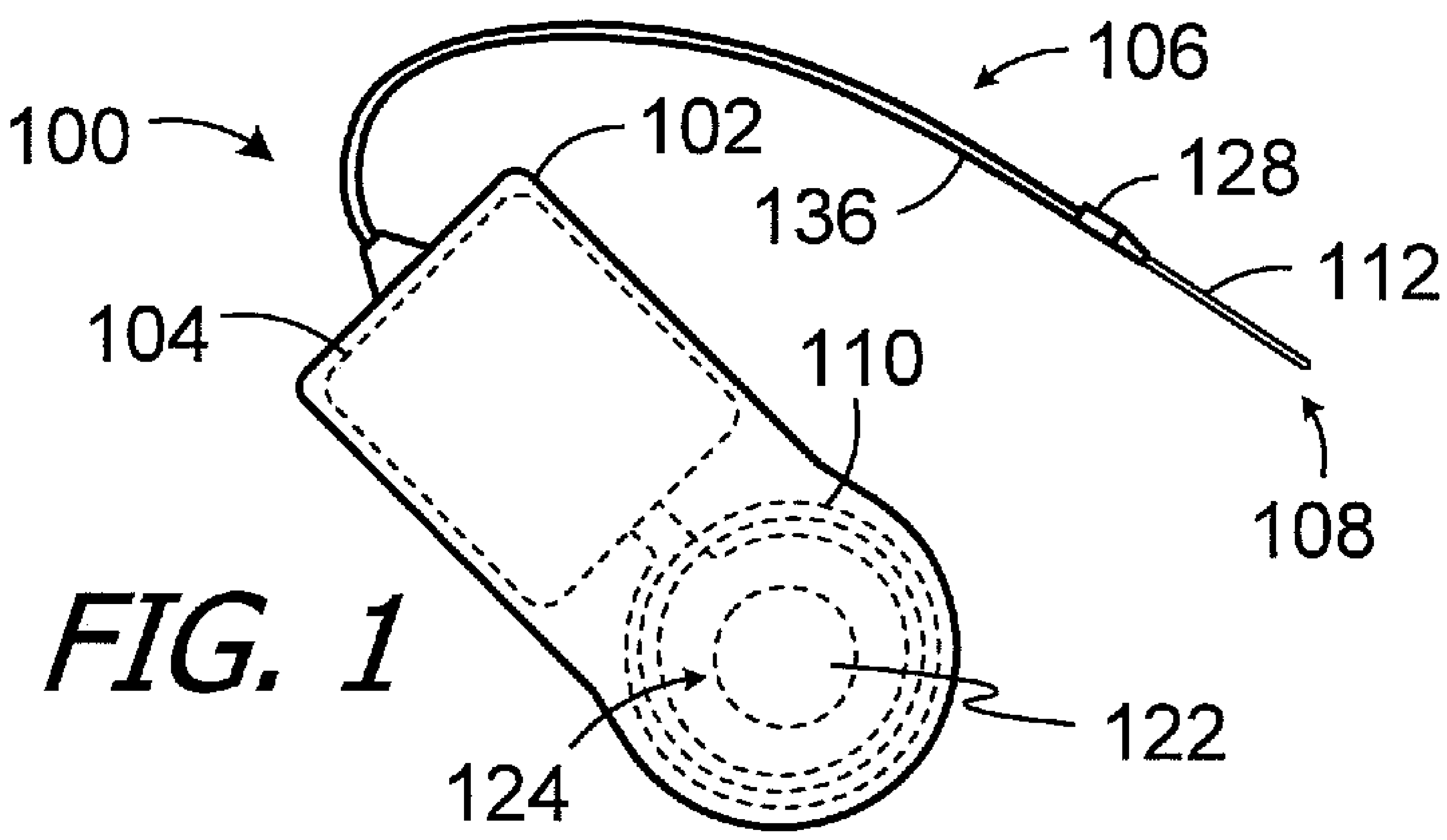


FIG. 1

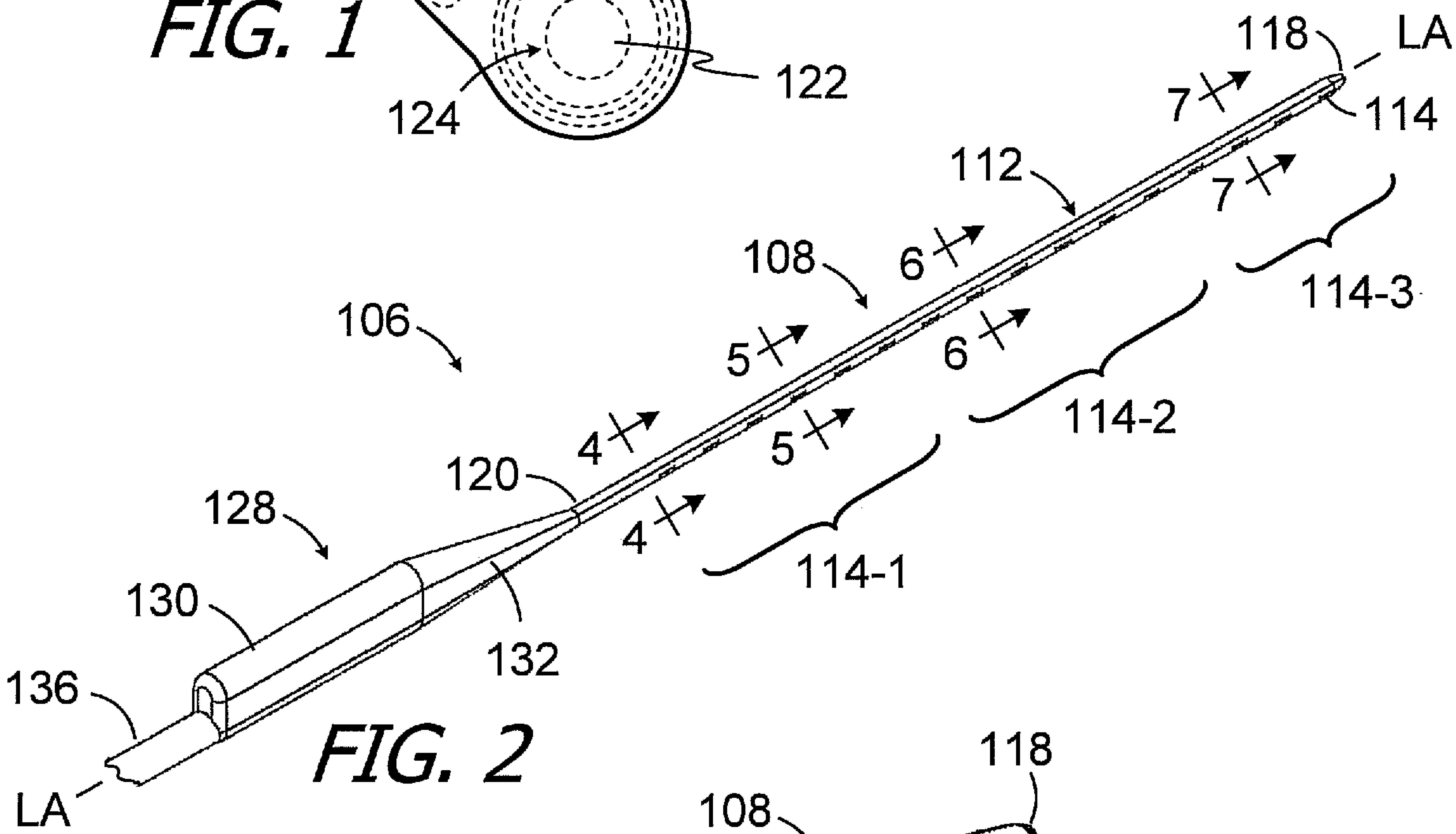
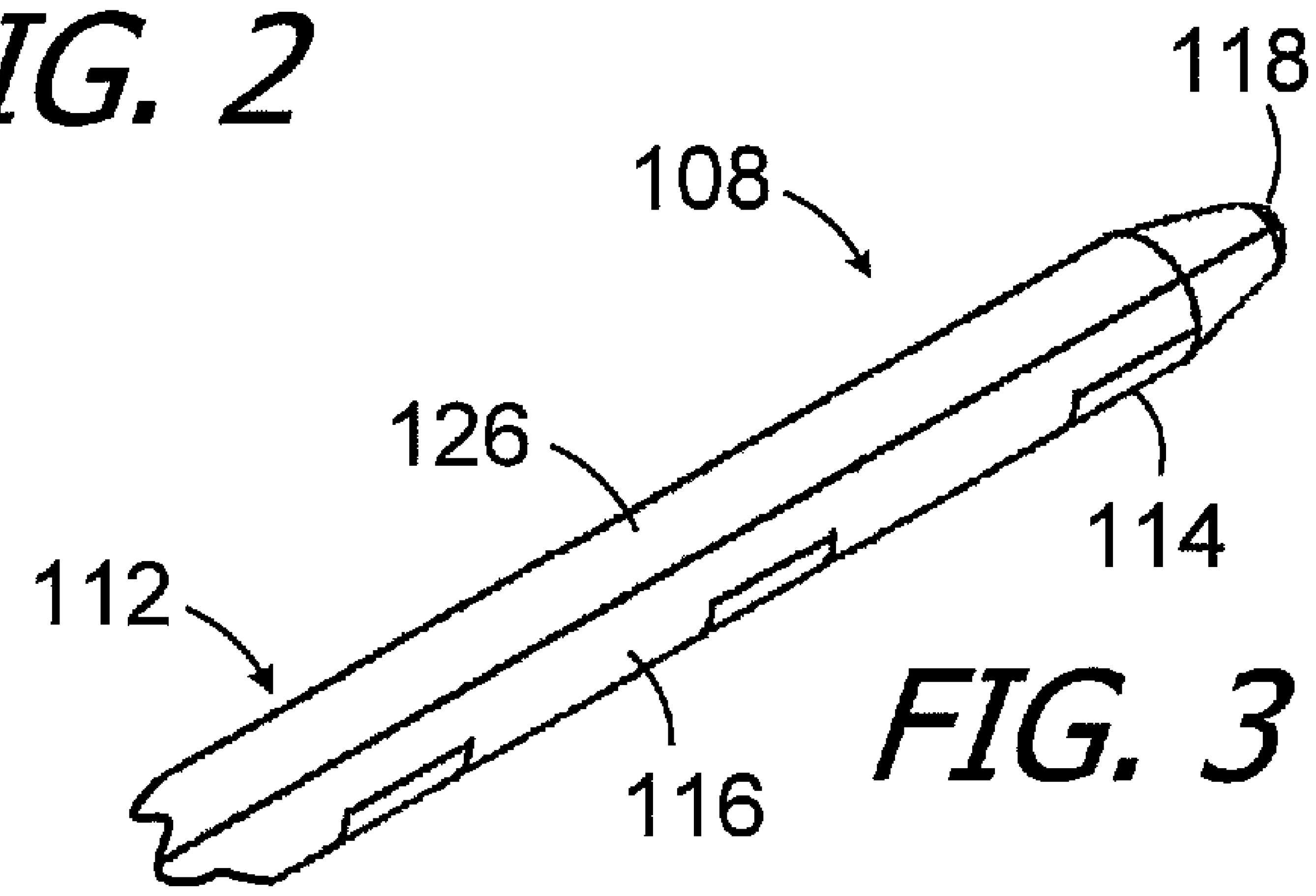


FIG. 2



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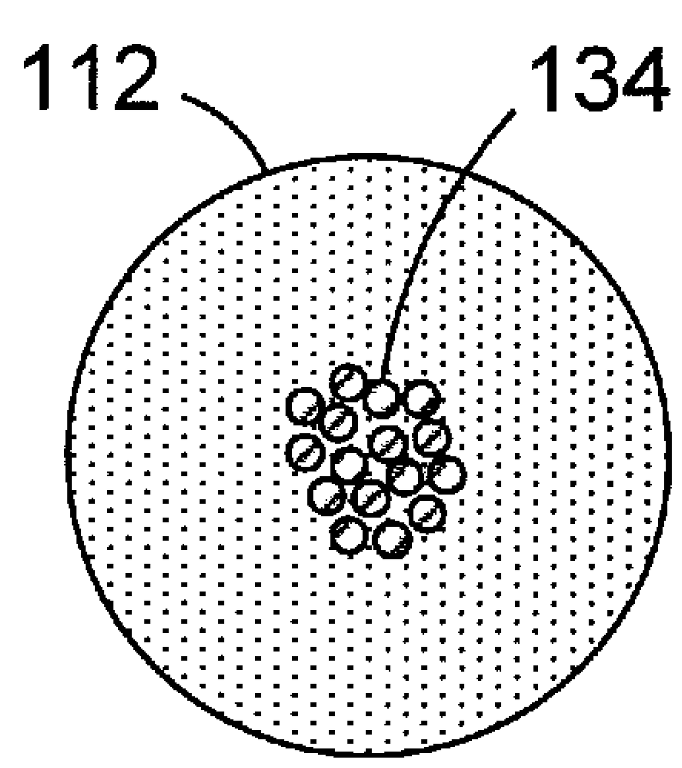

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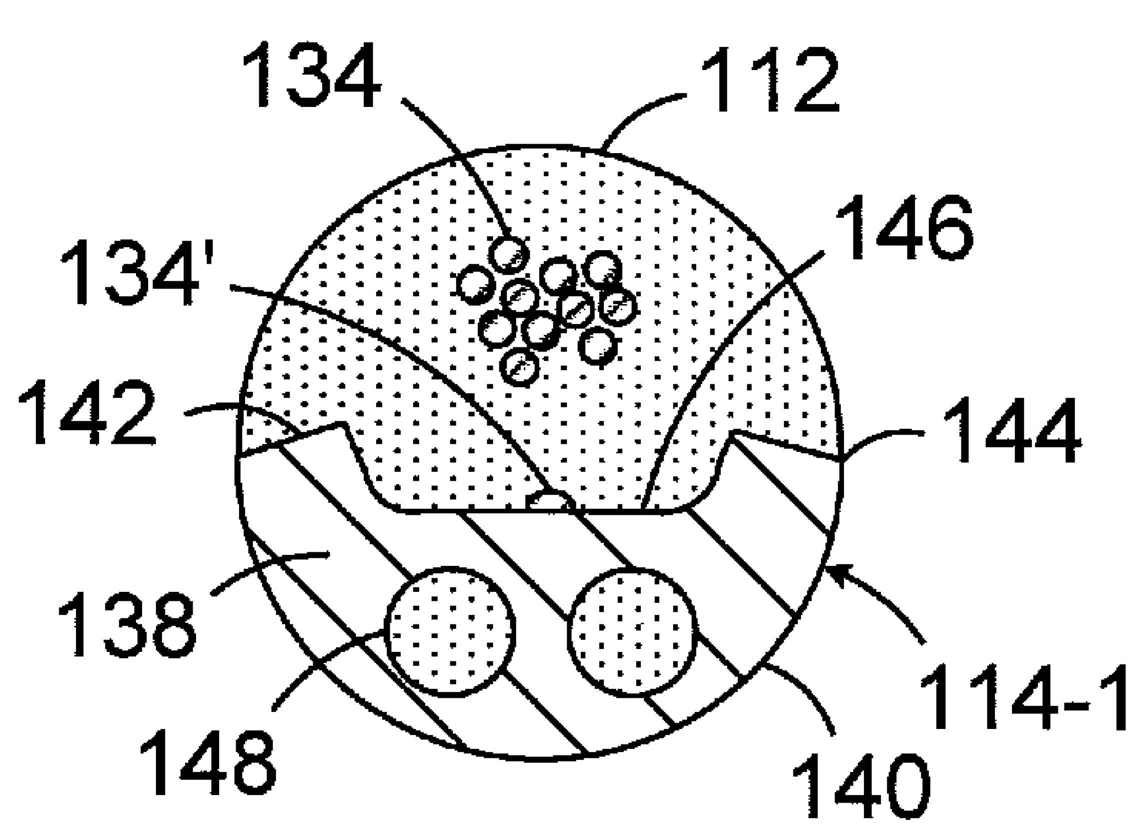

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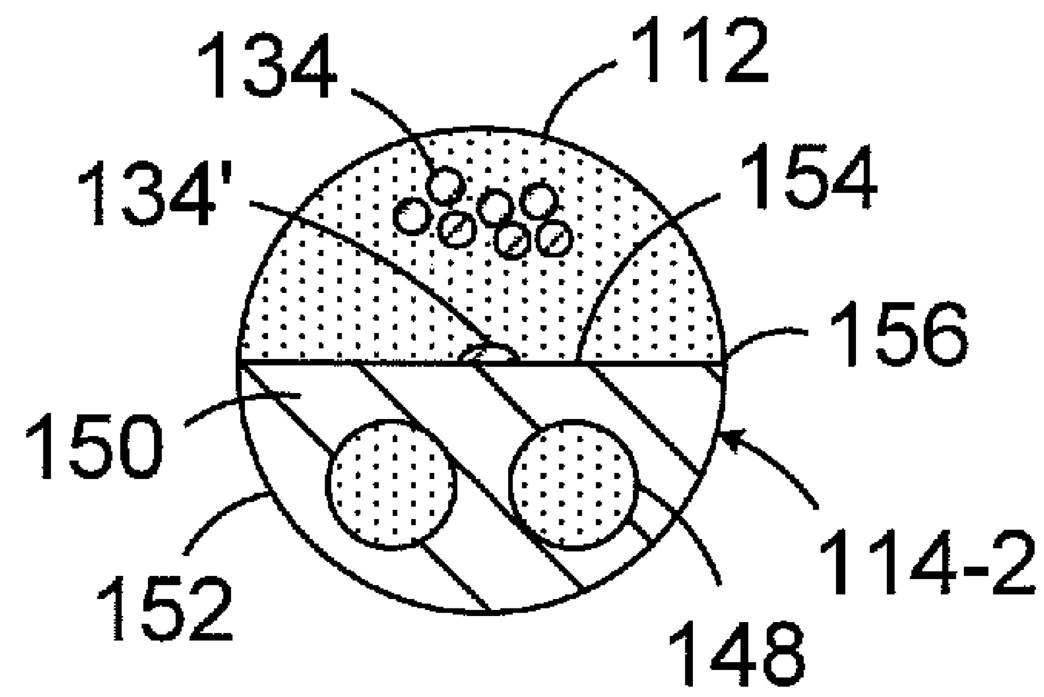

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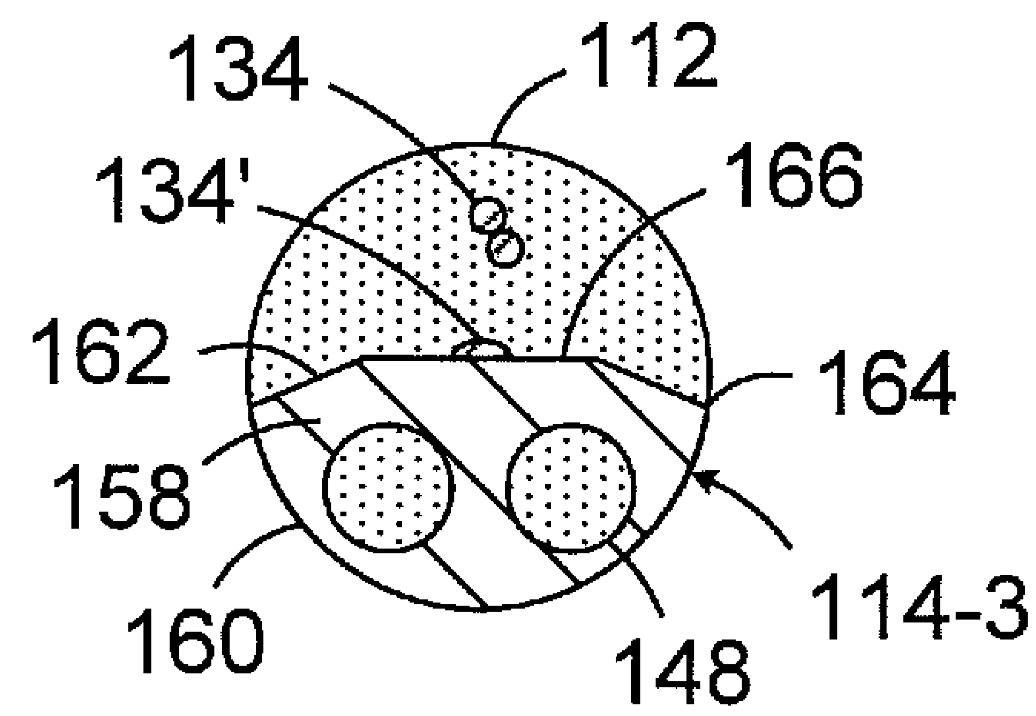

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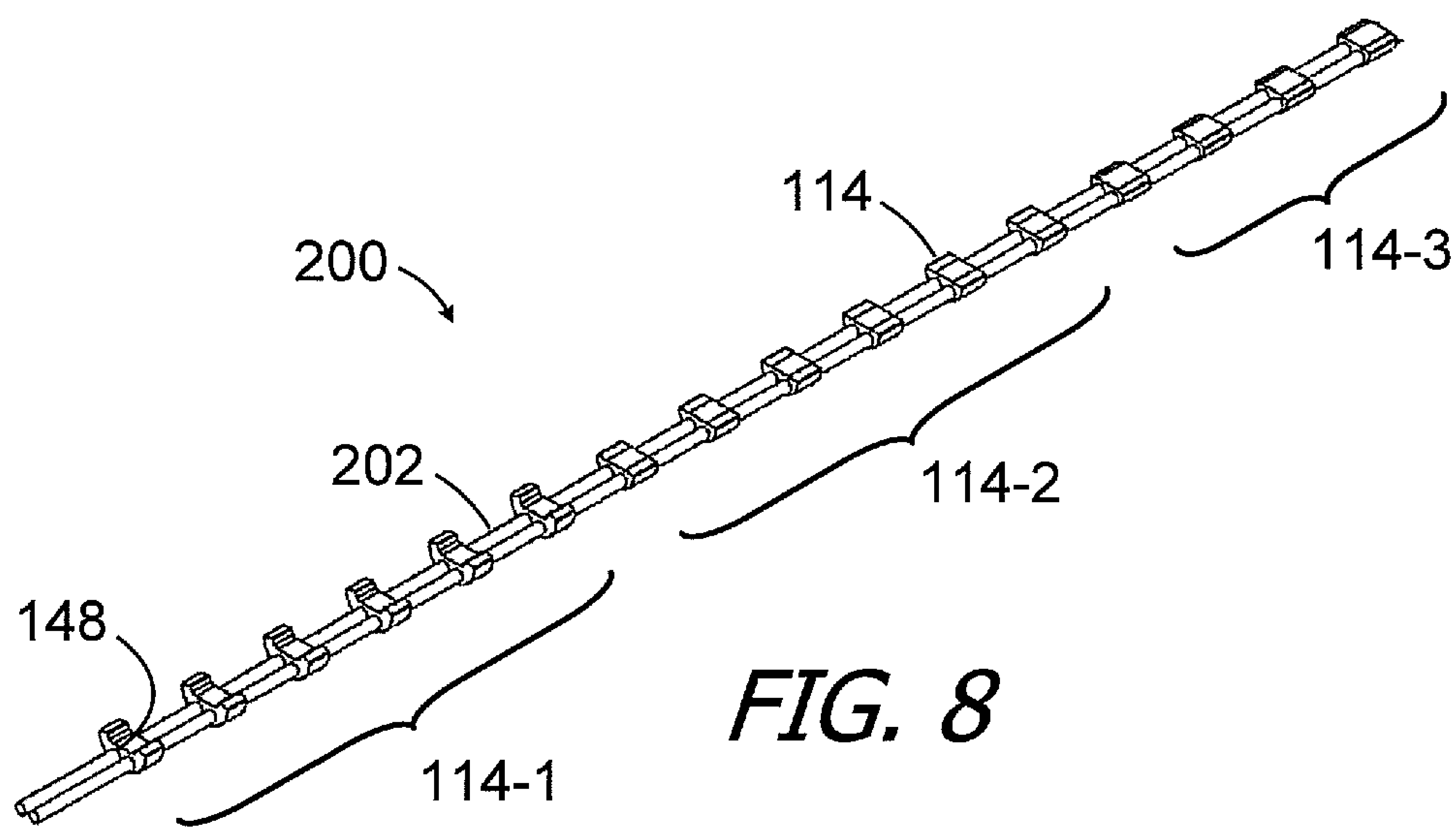

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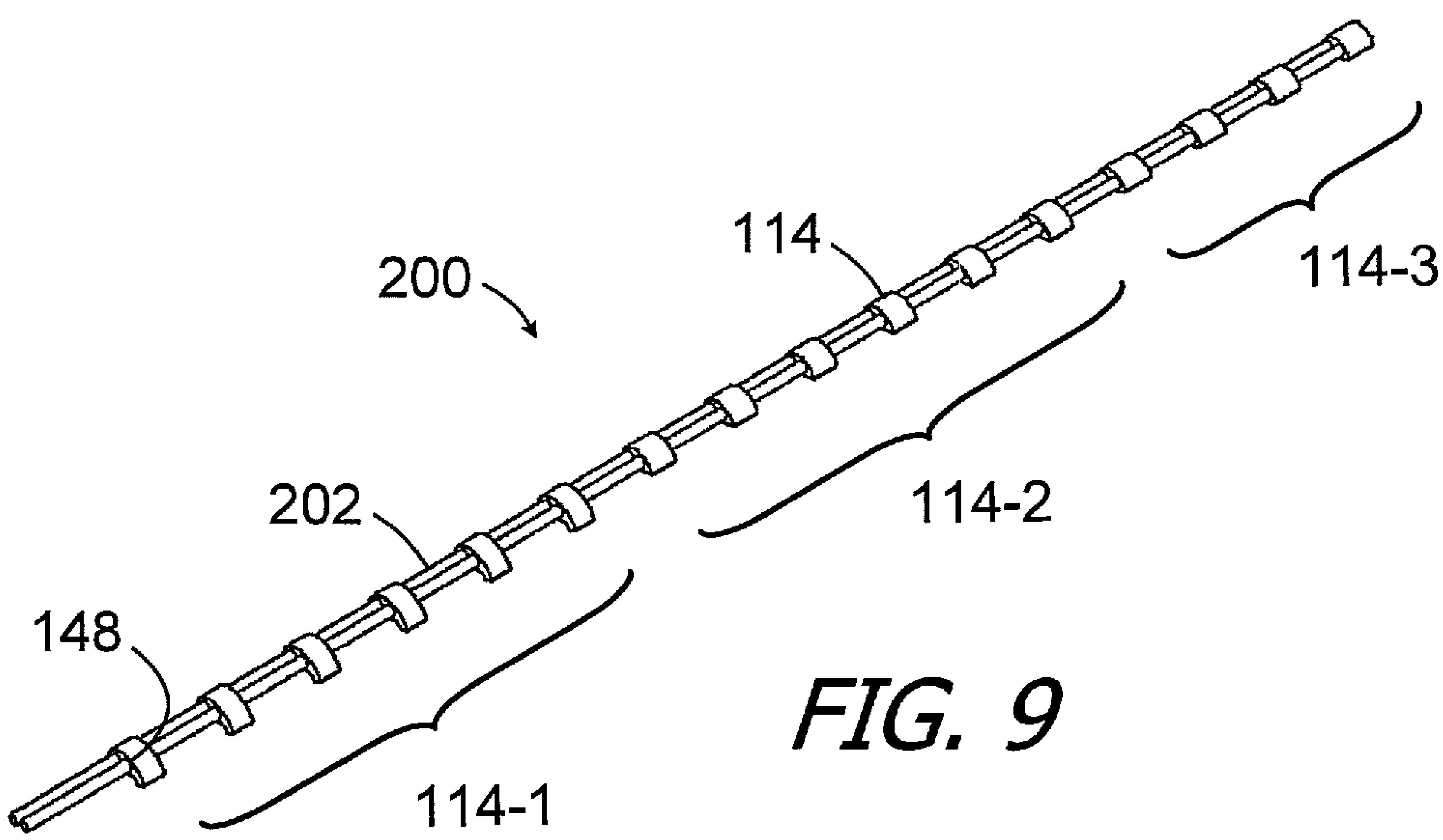

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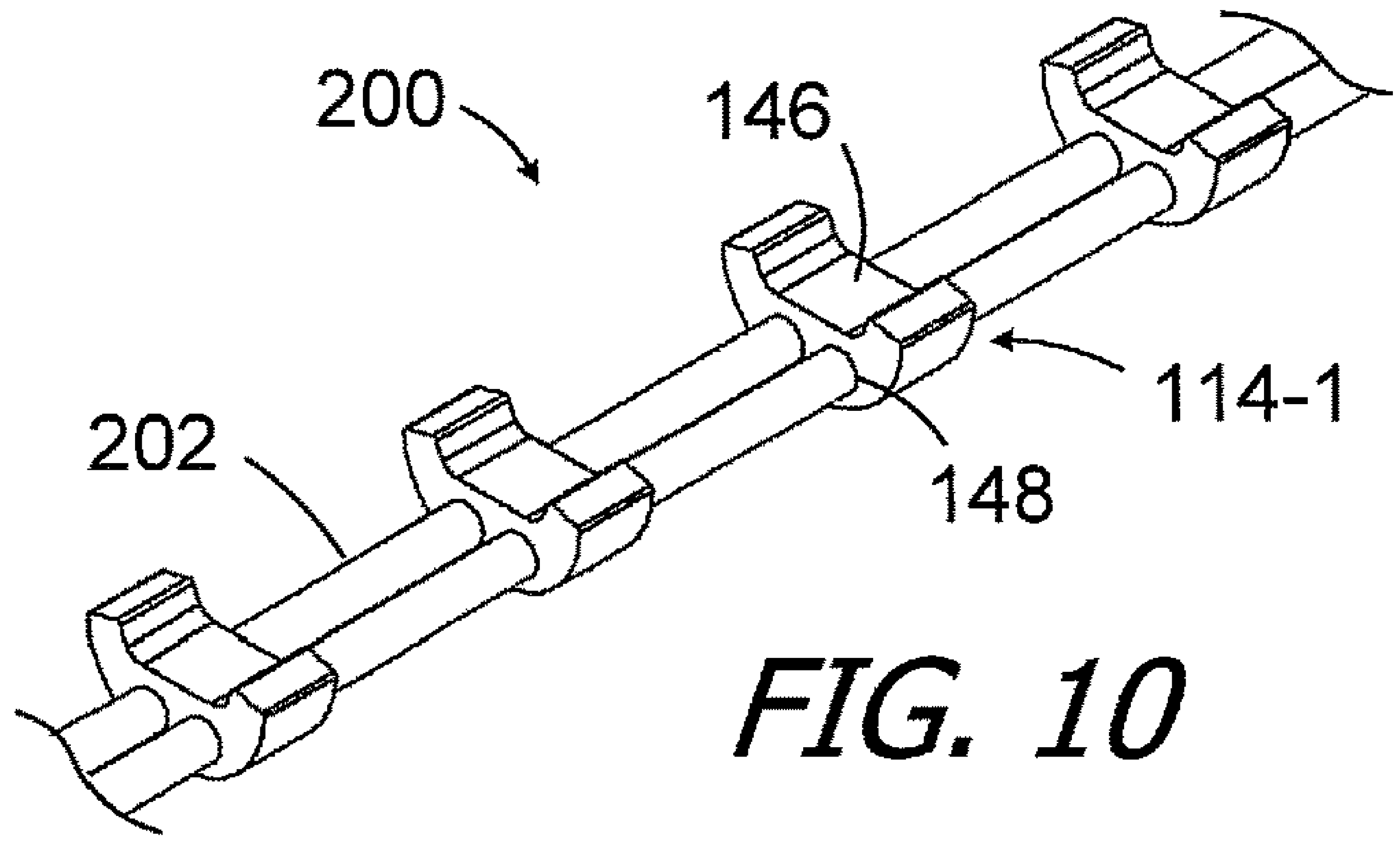

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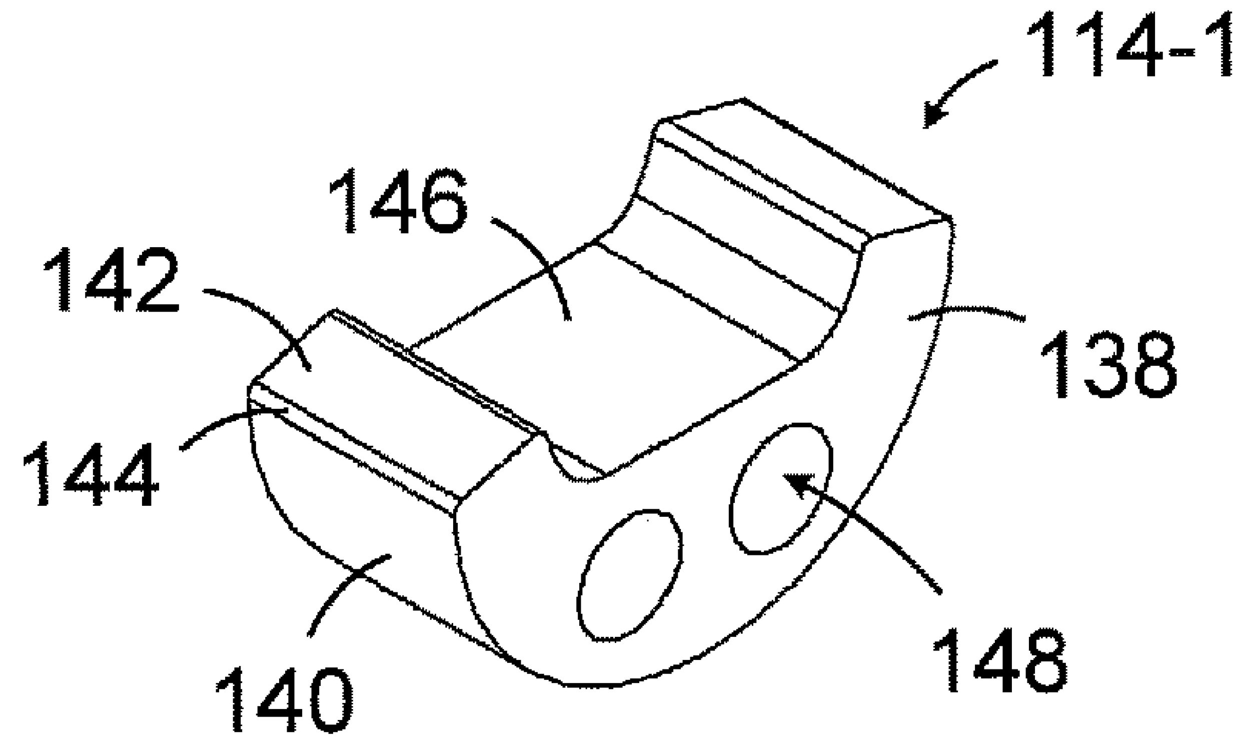

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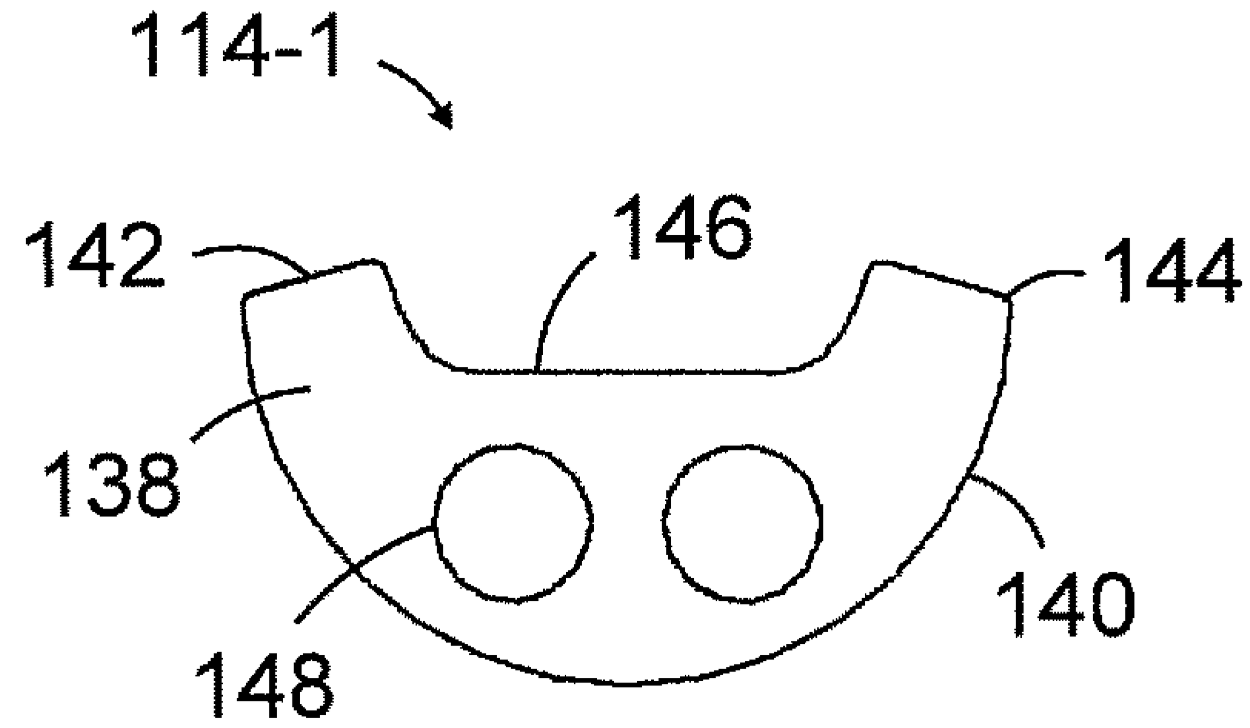

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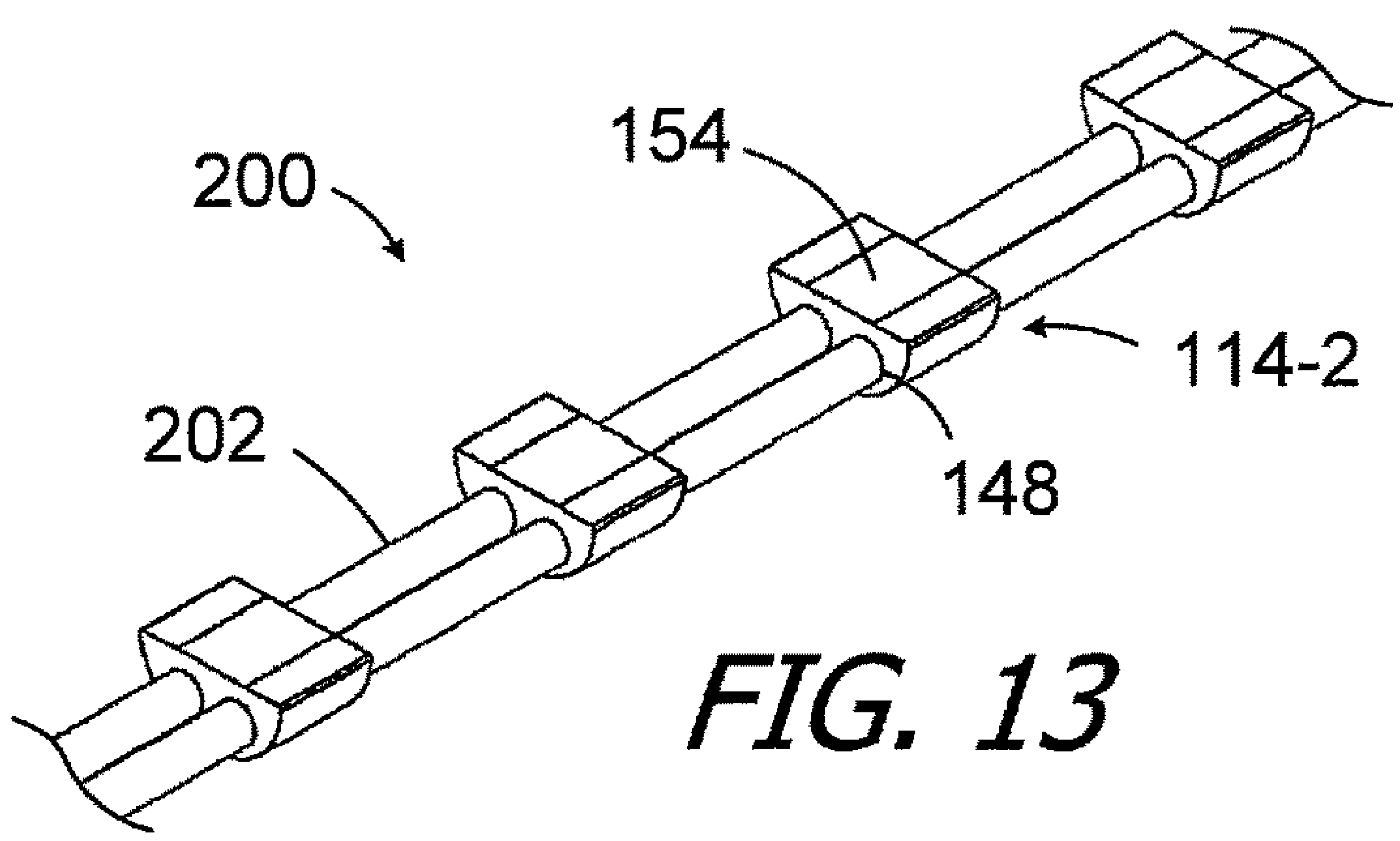

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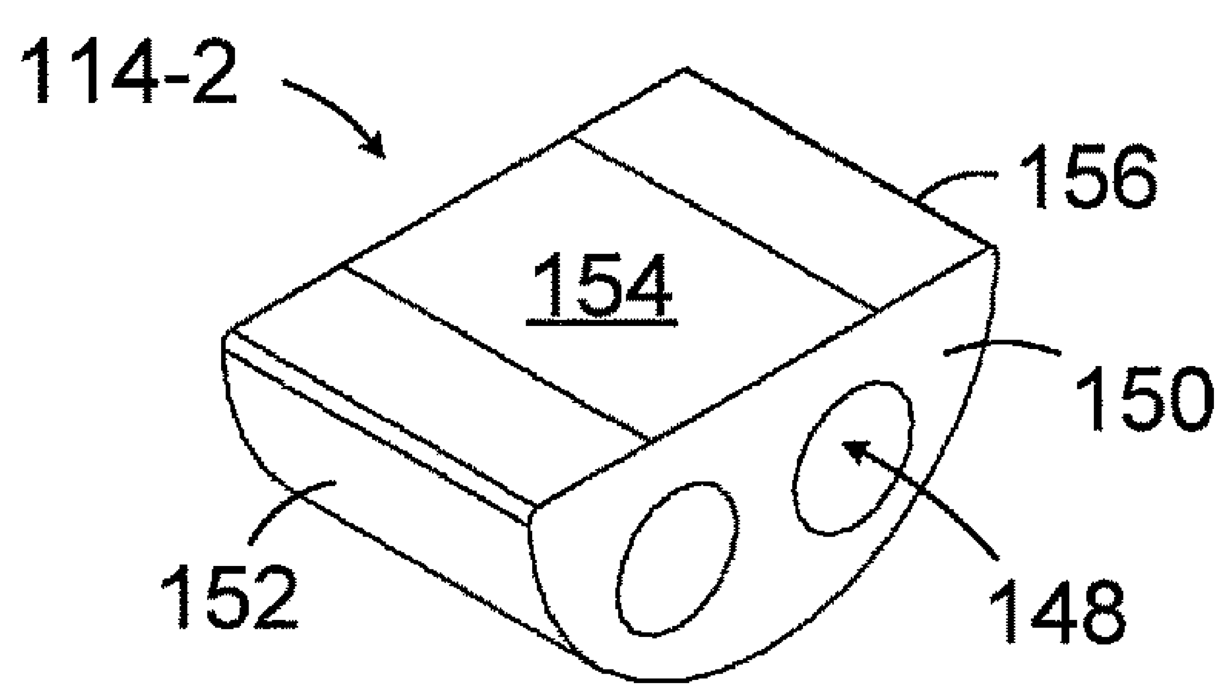

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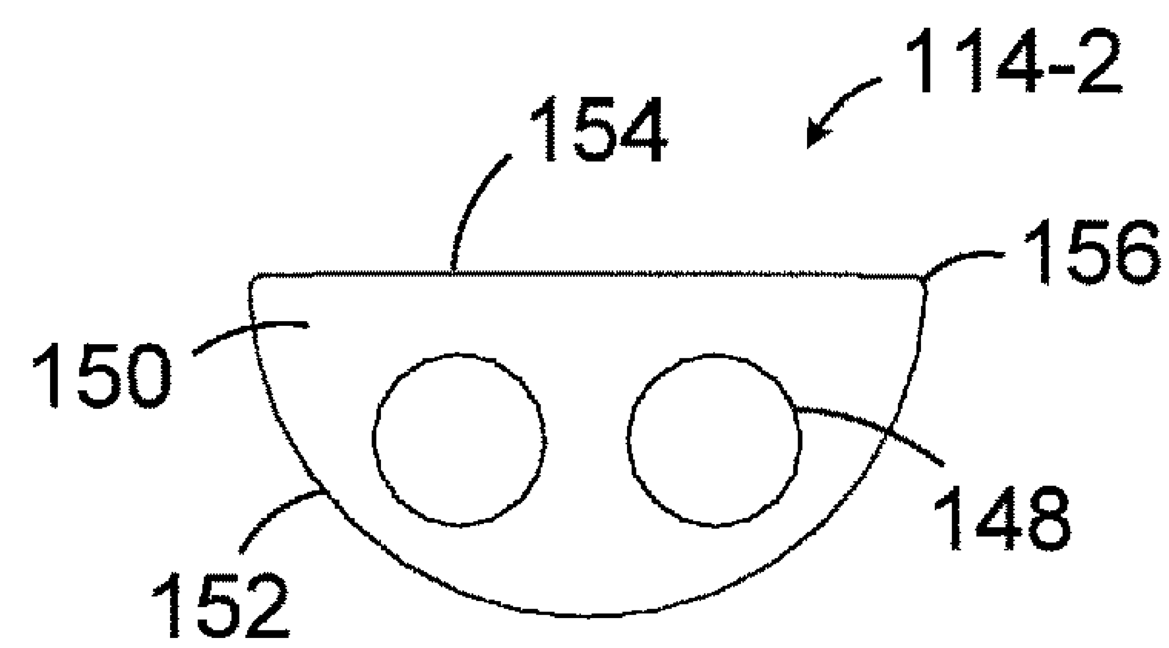

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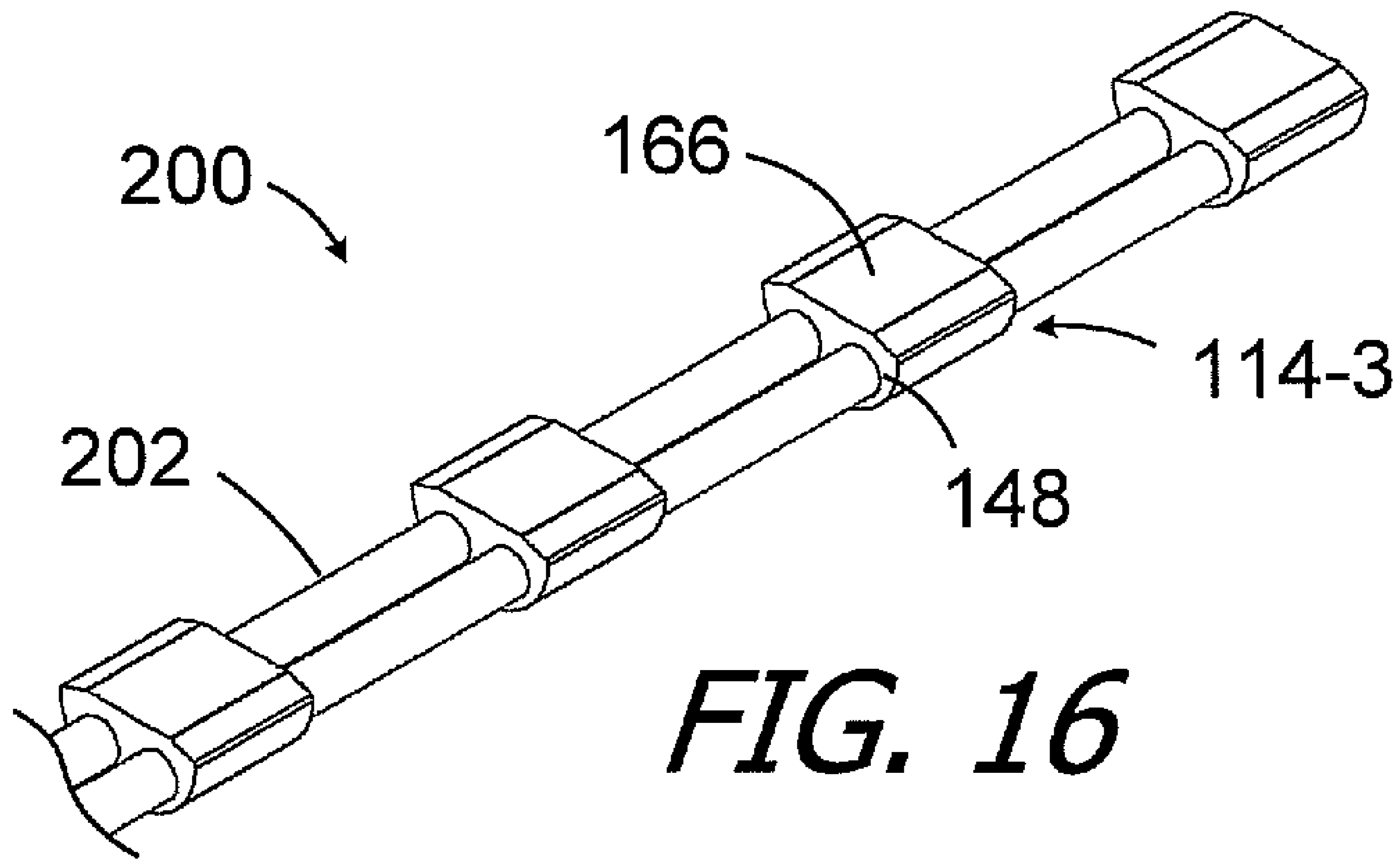

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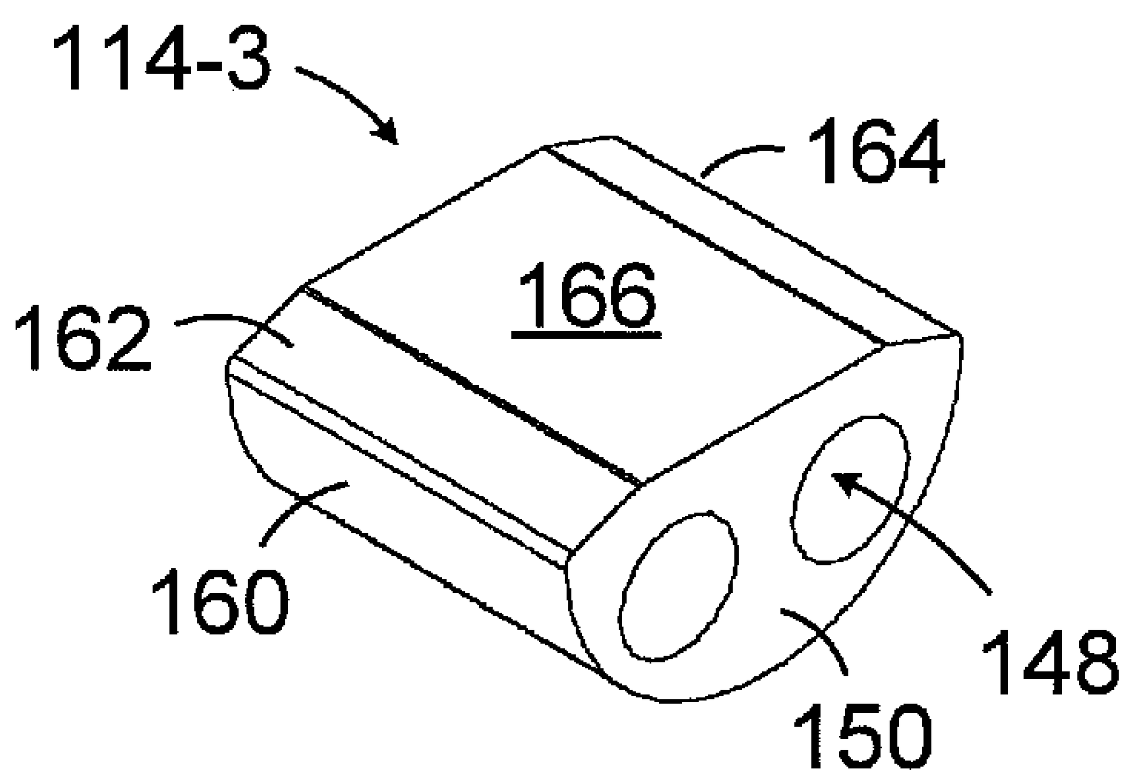

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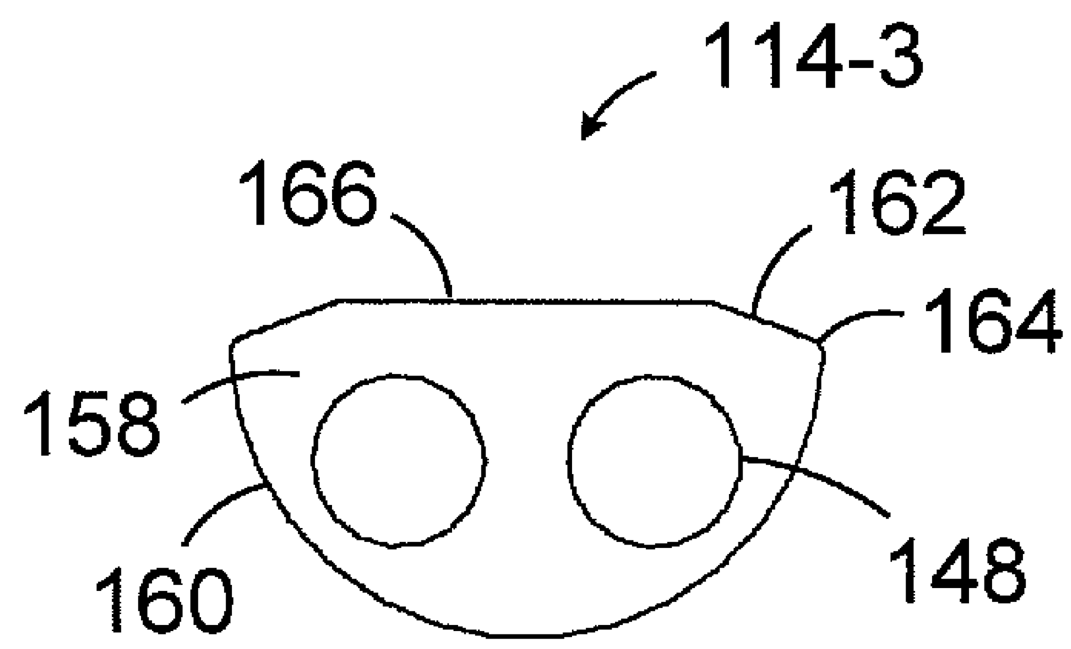

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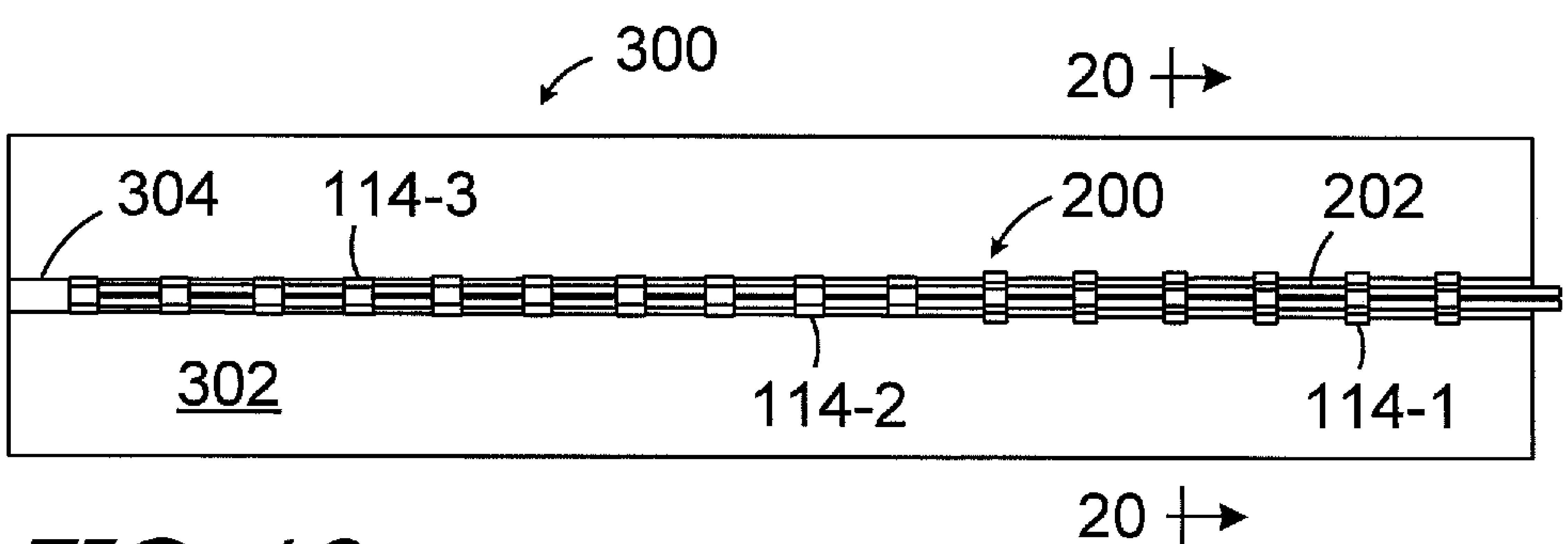

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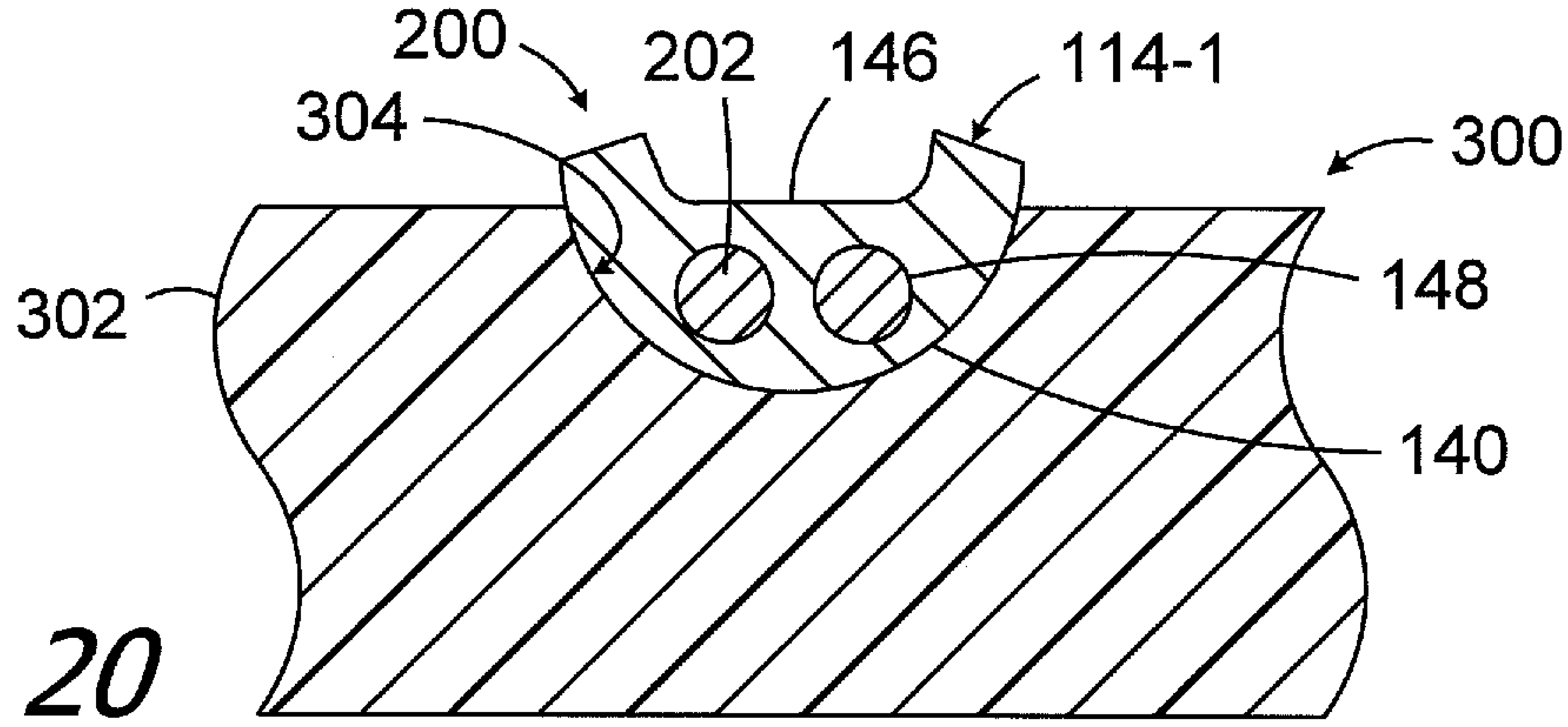

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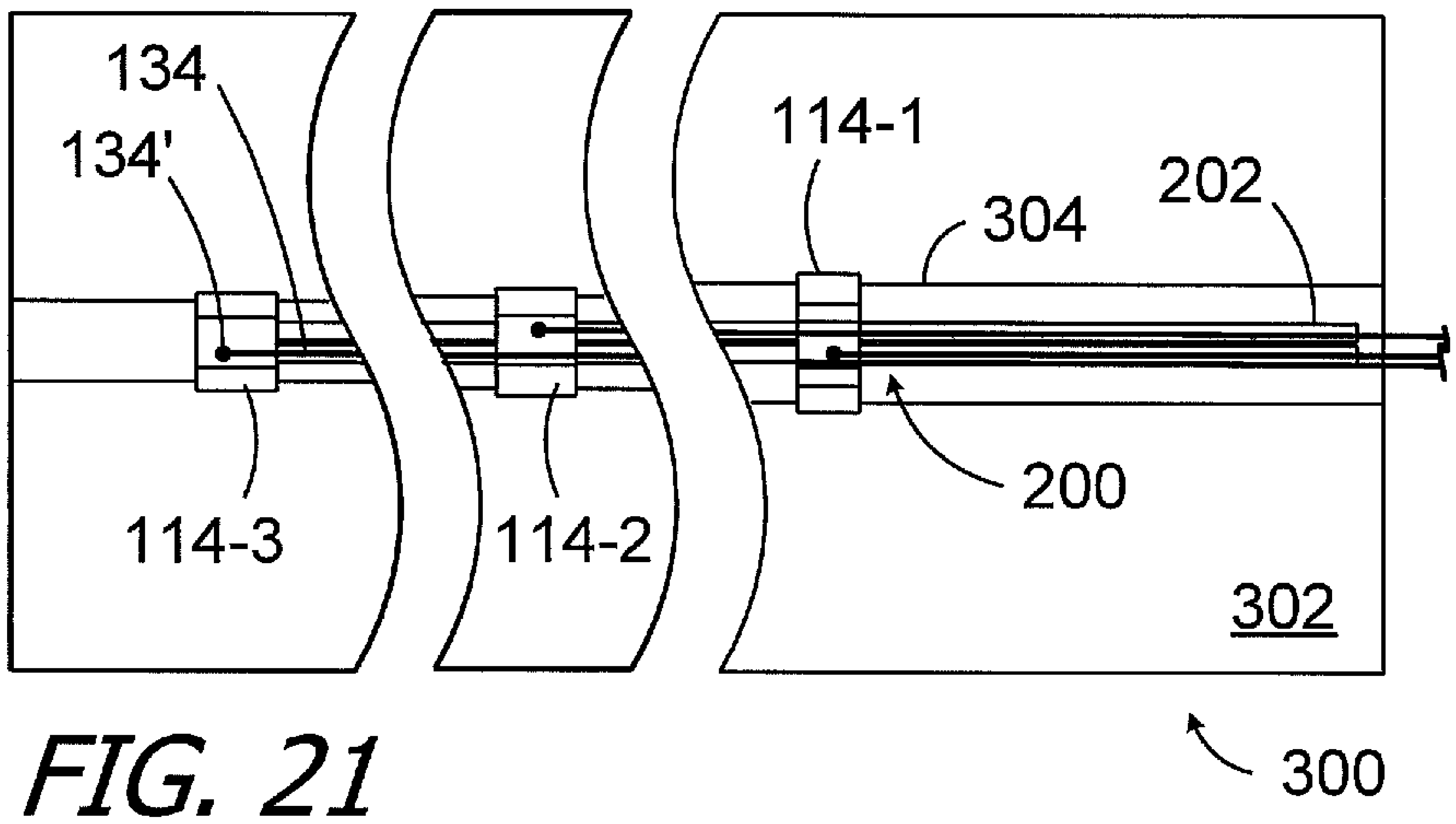

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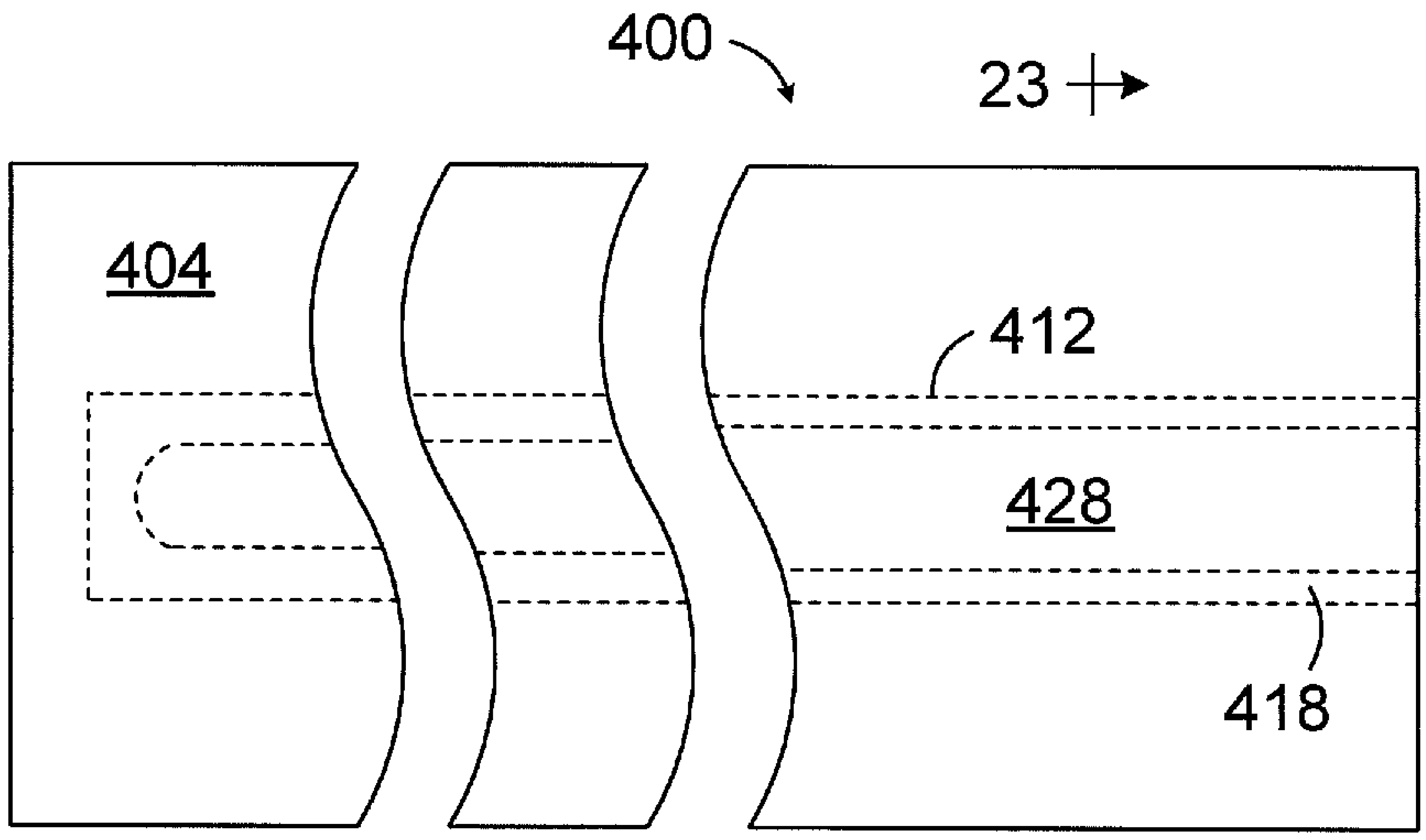

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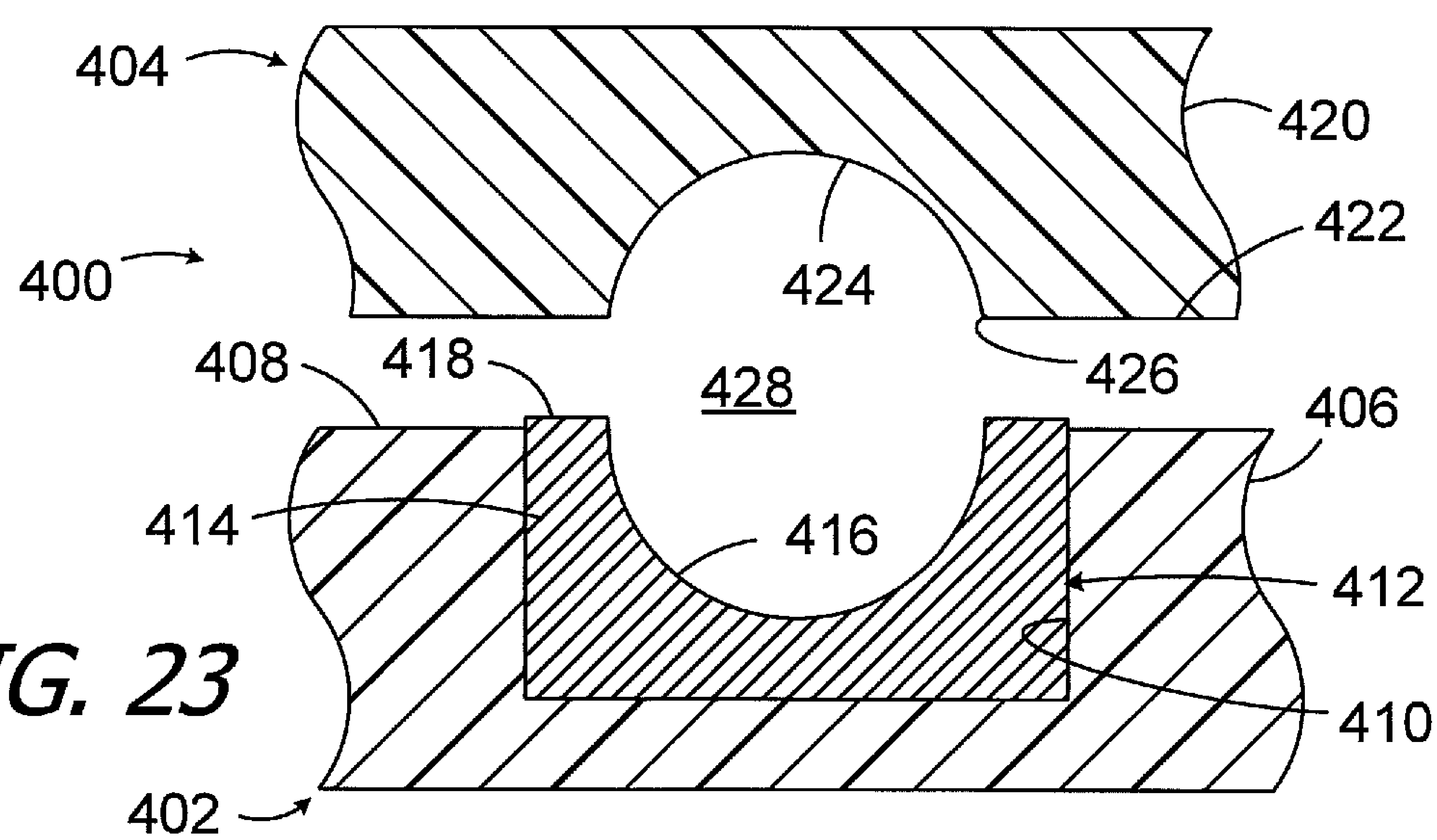

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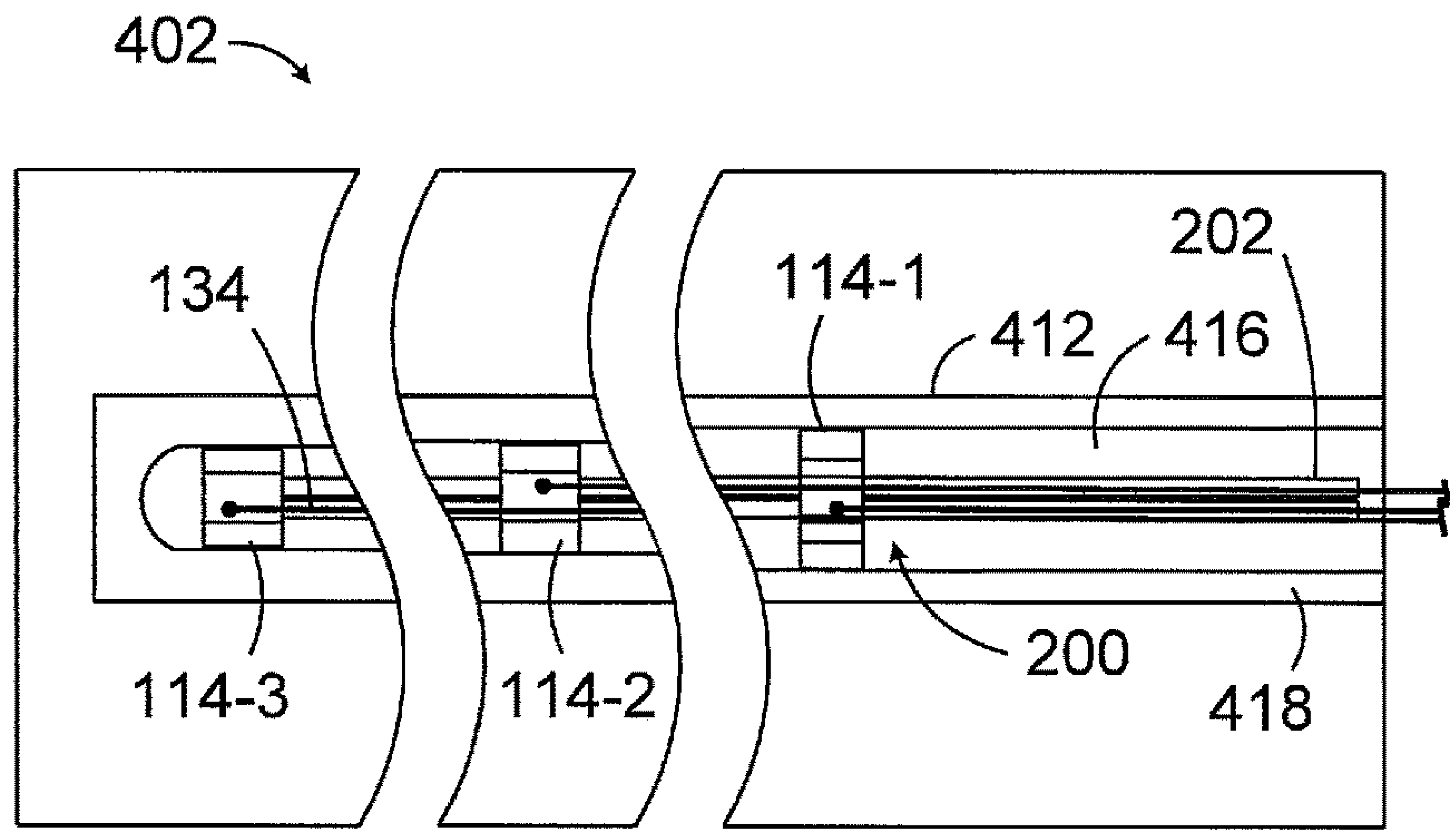

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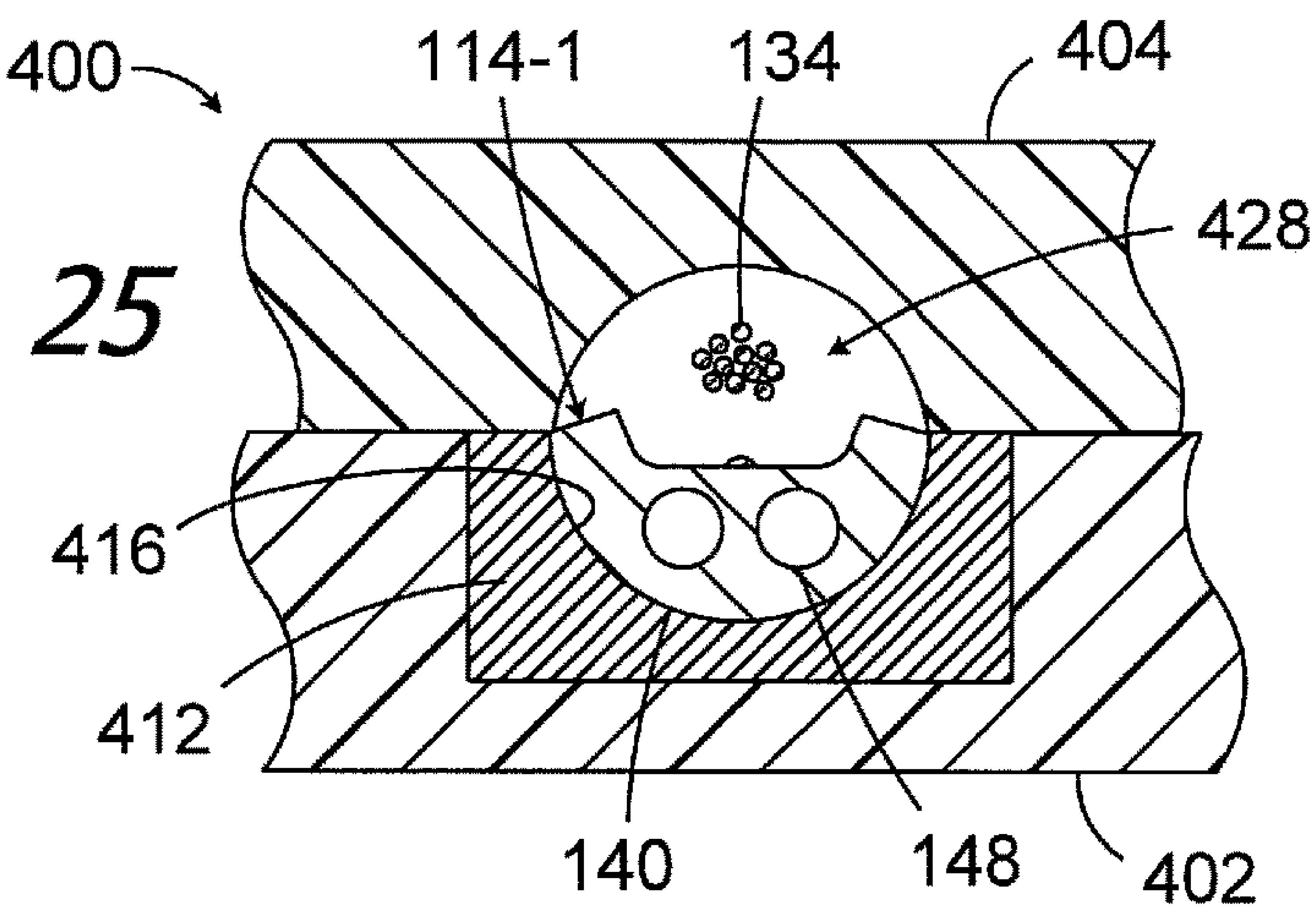

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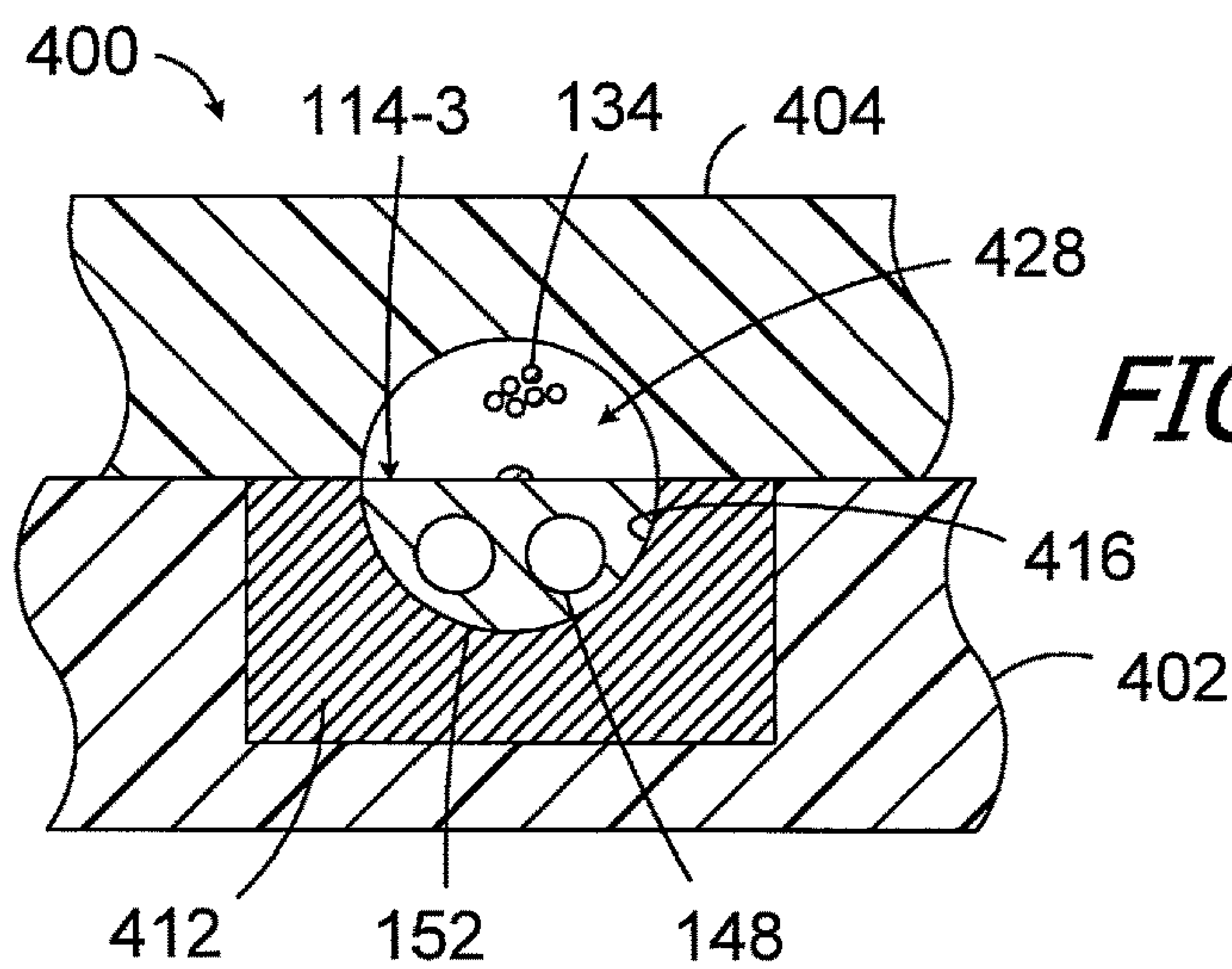
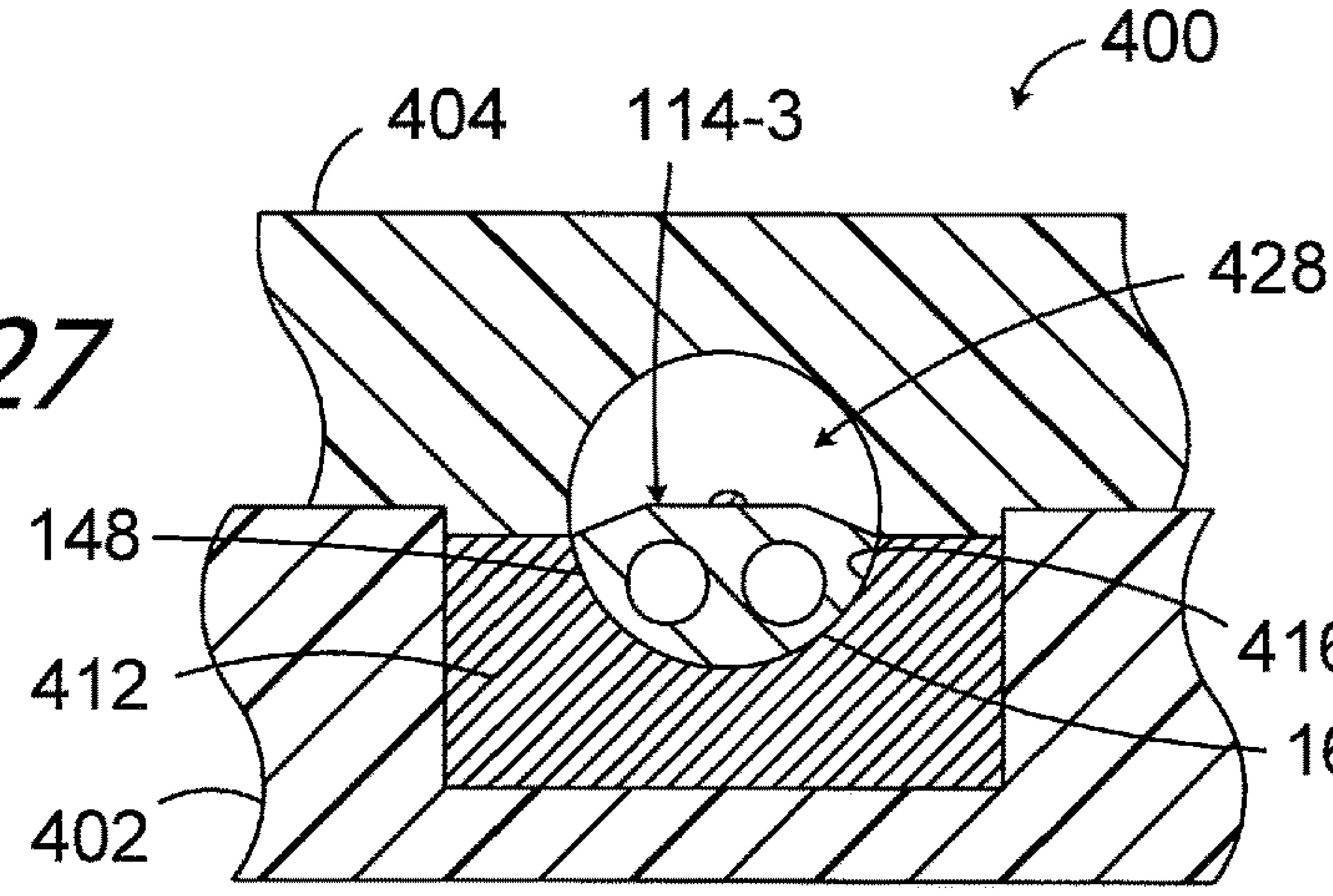
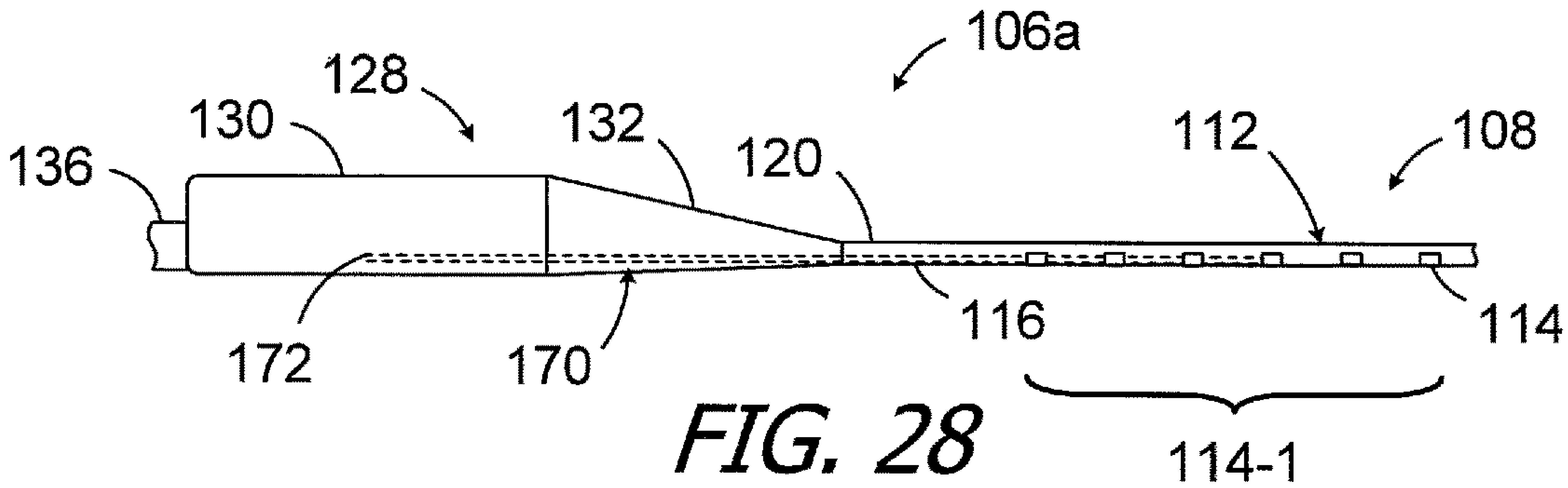


FIG. 26

FIG. 27





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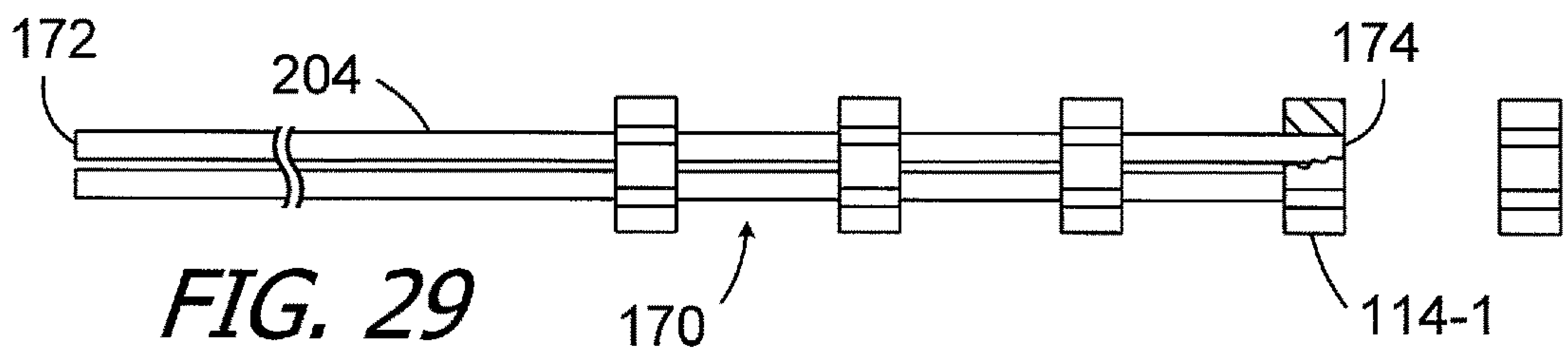

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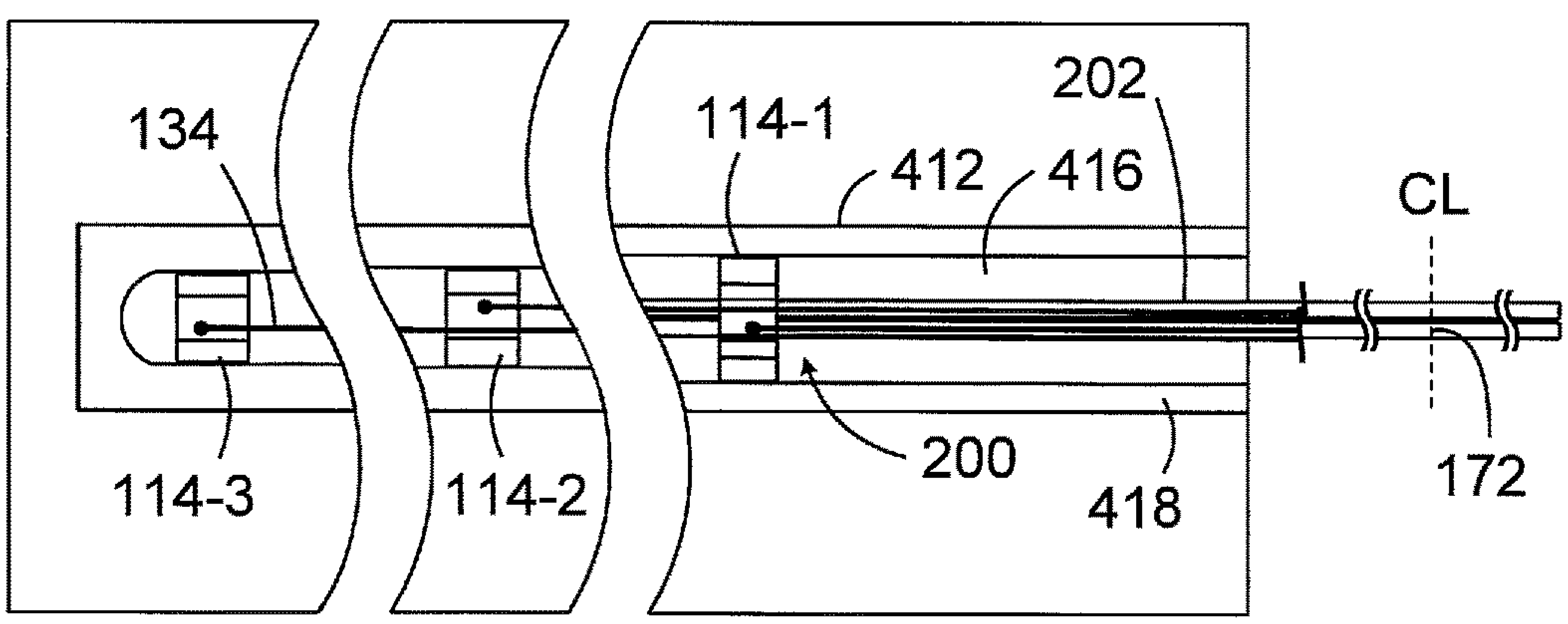

FIG. 30

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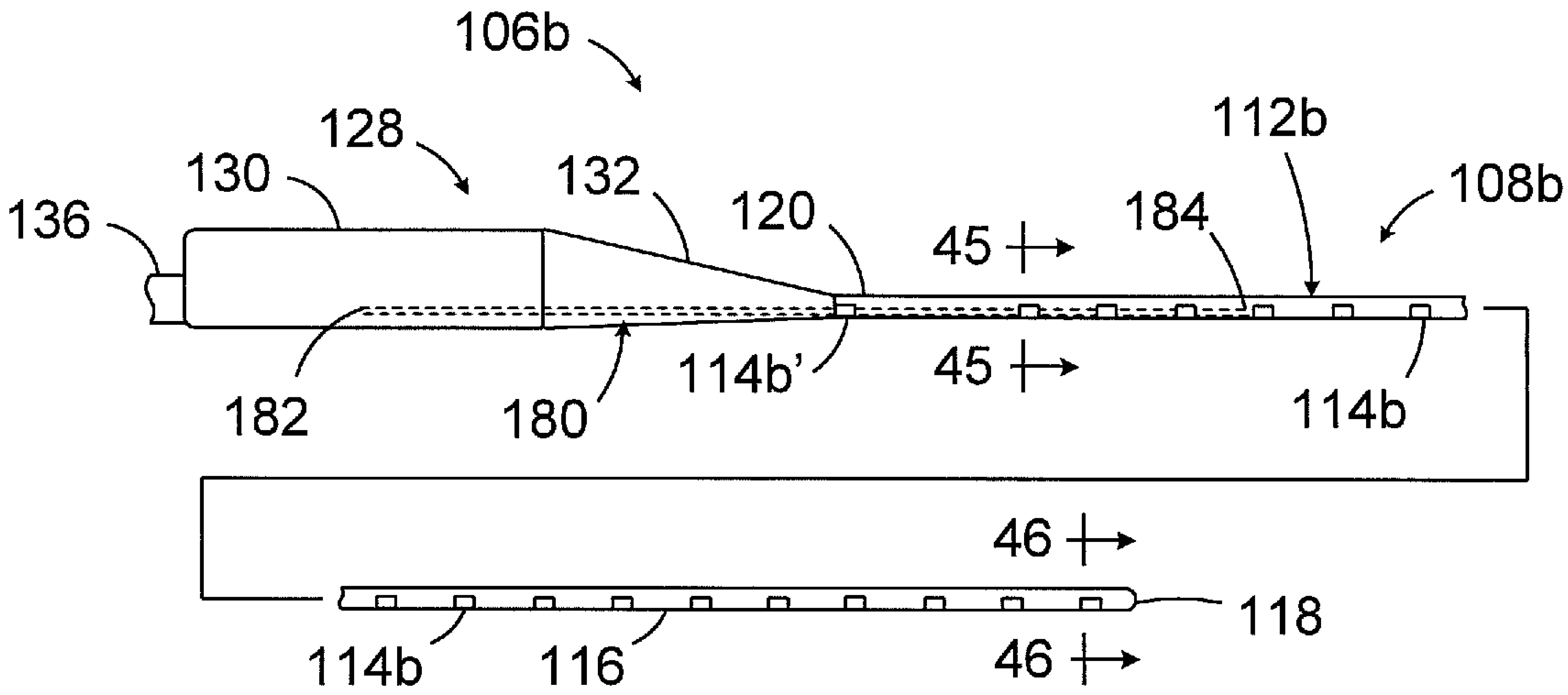

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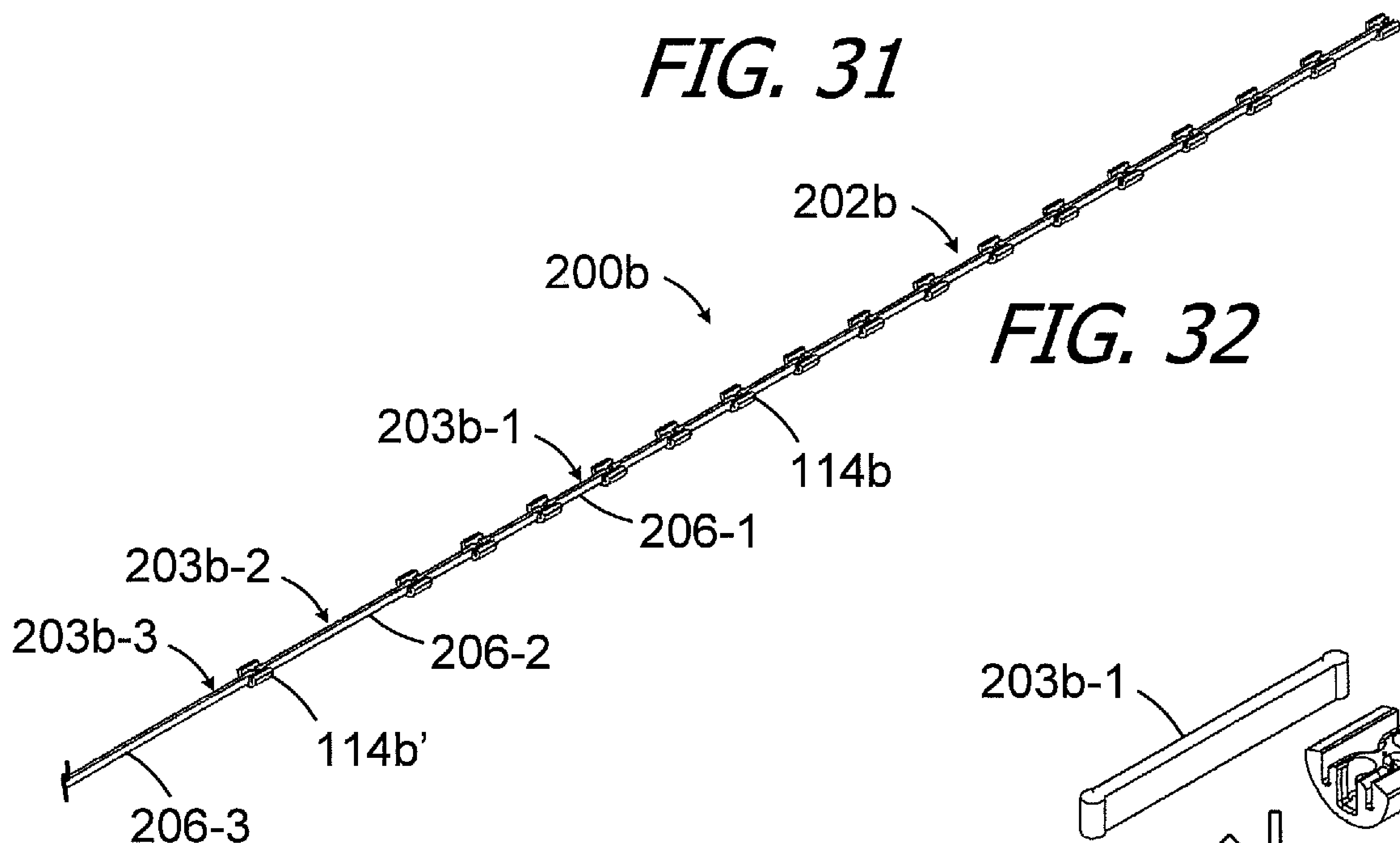

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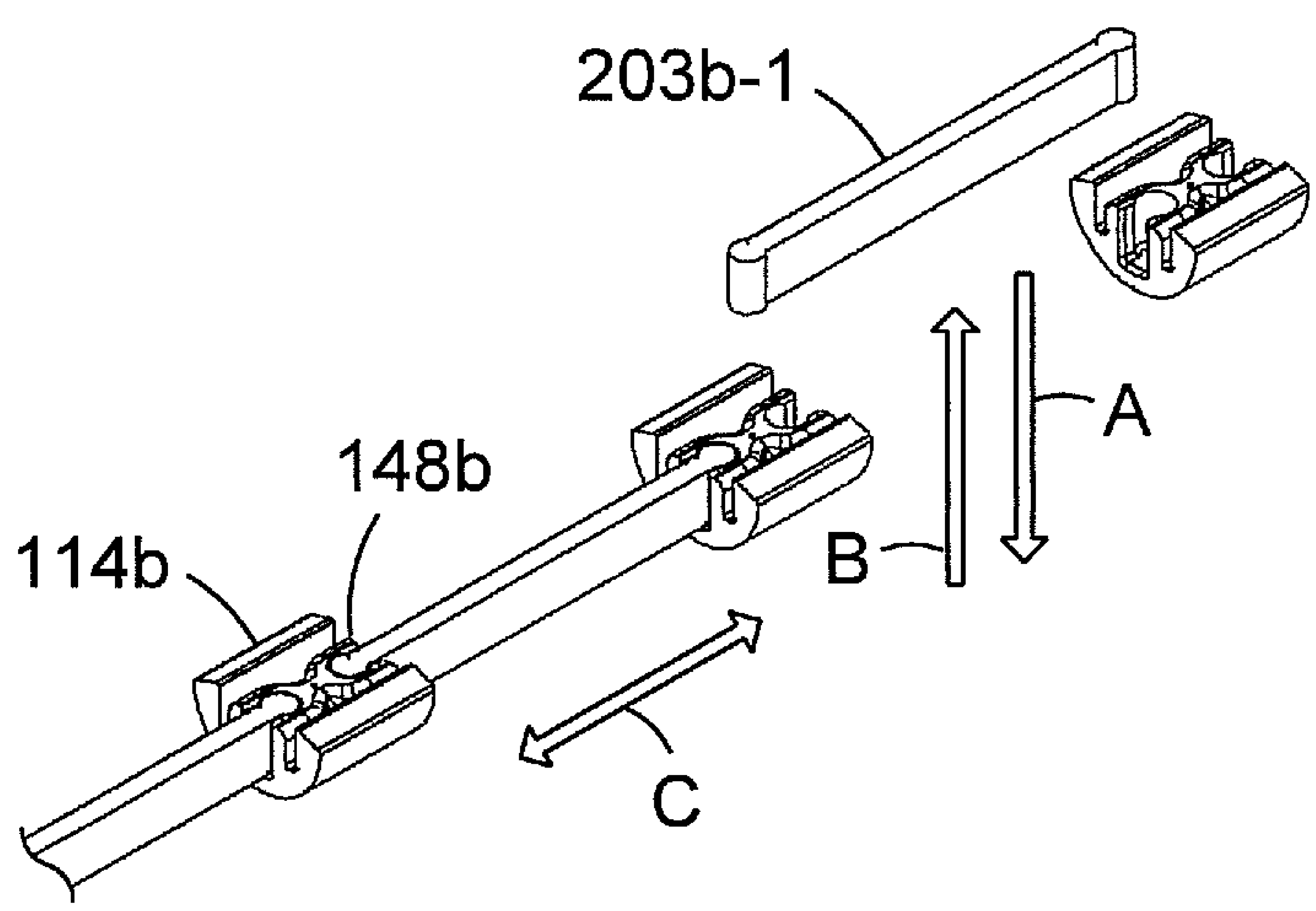

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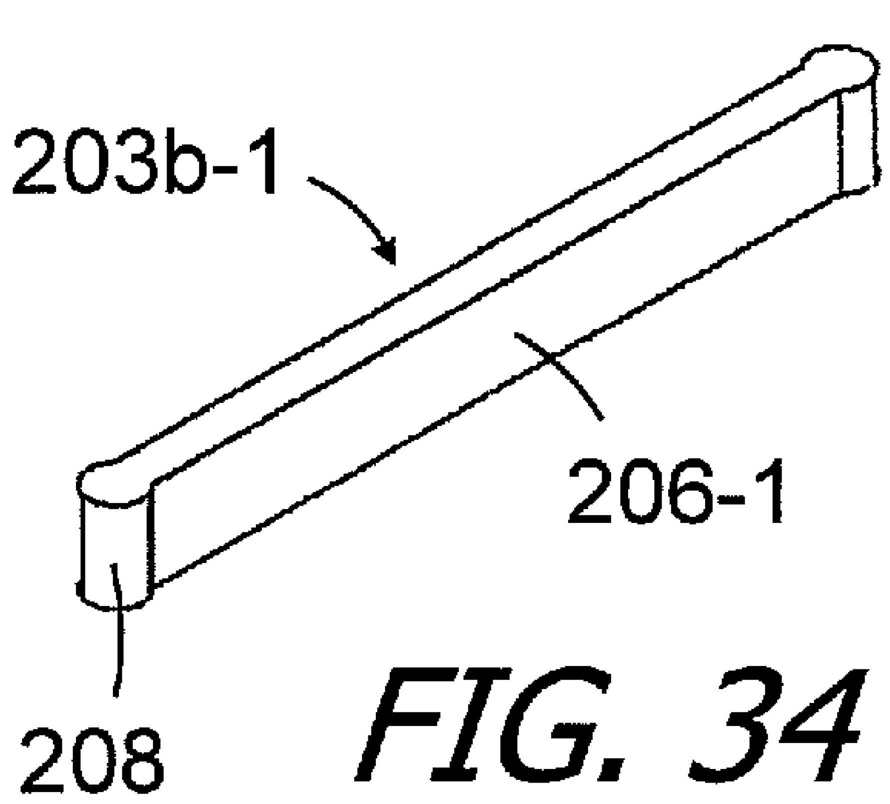

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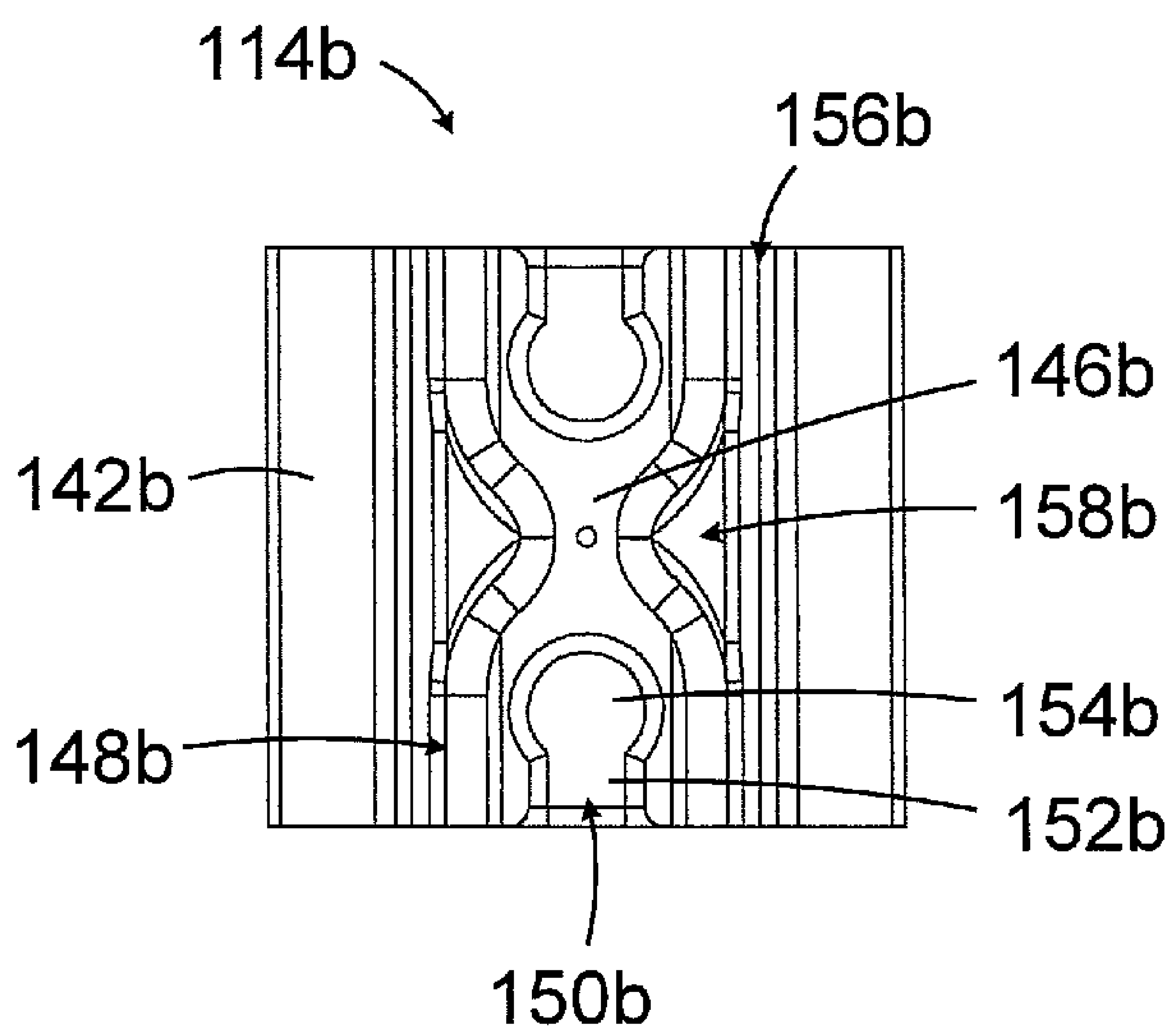

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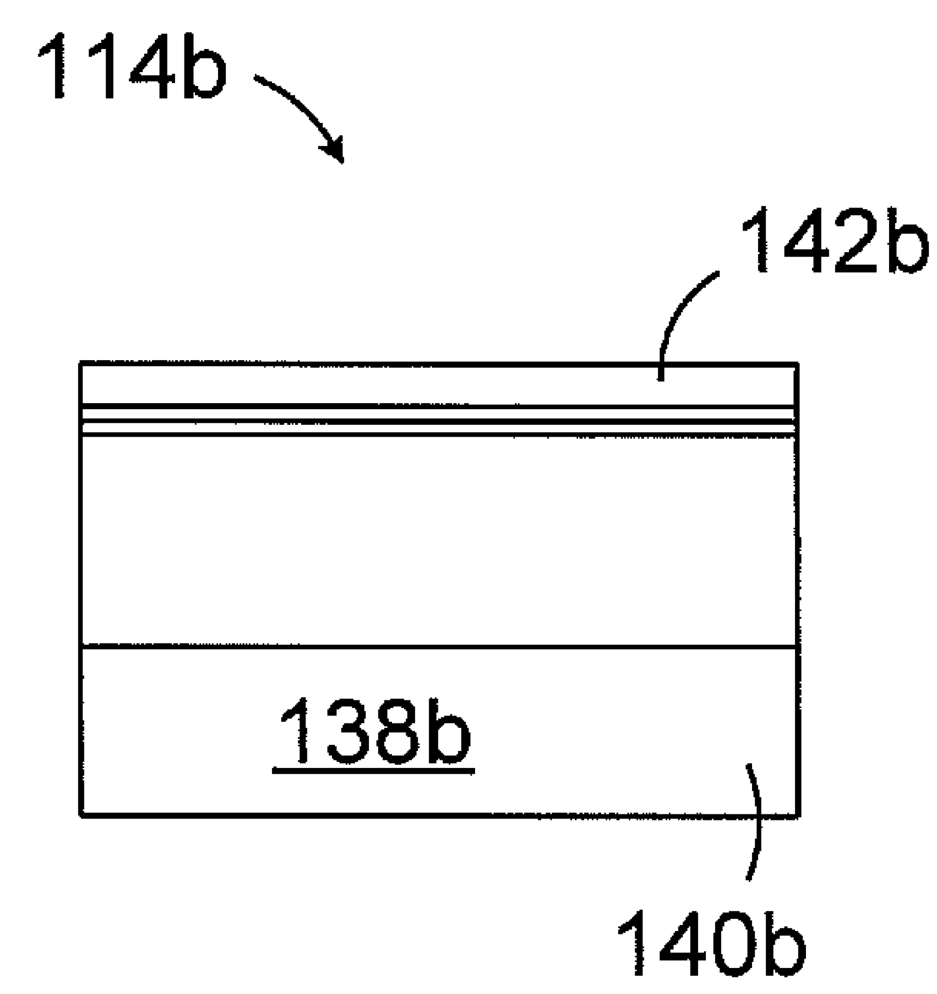

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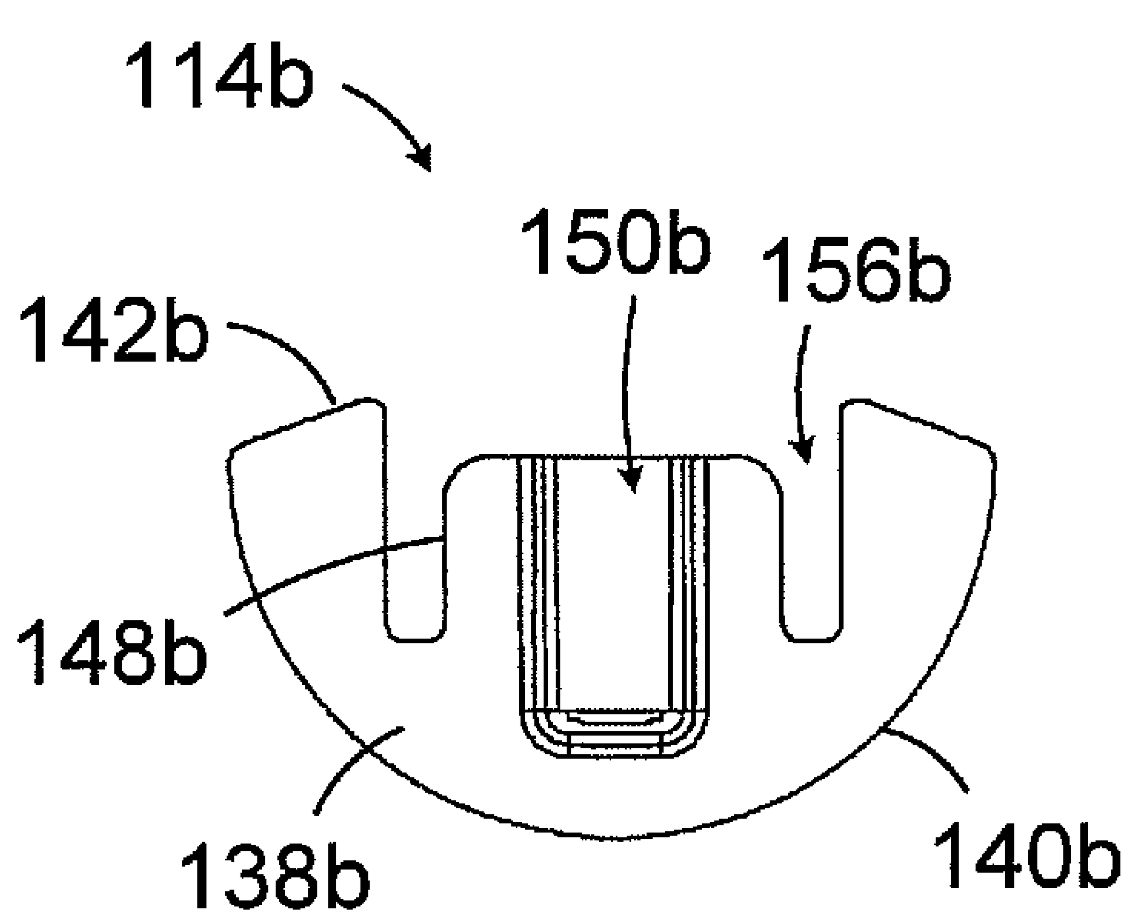

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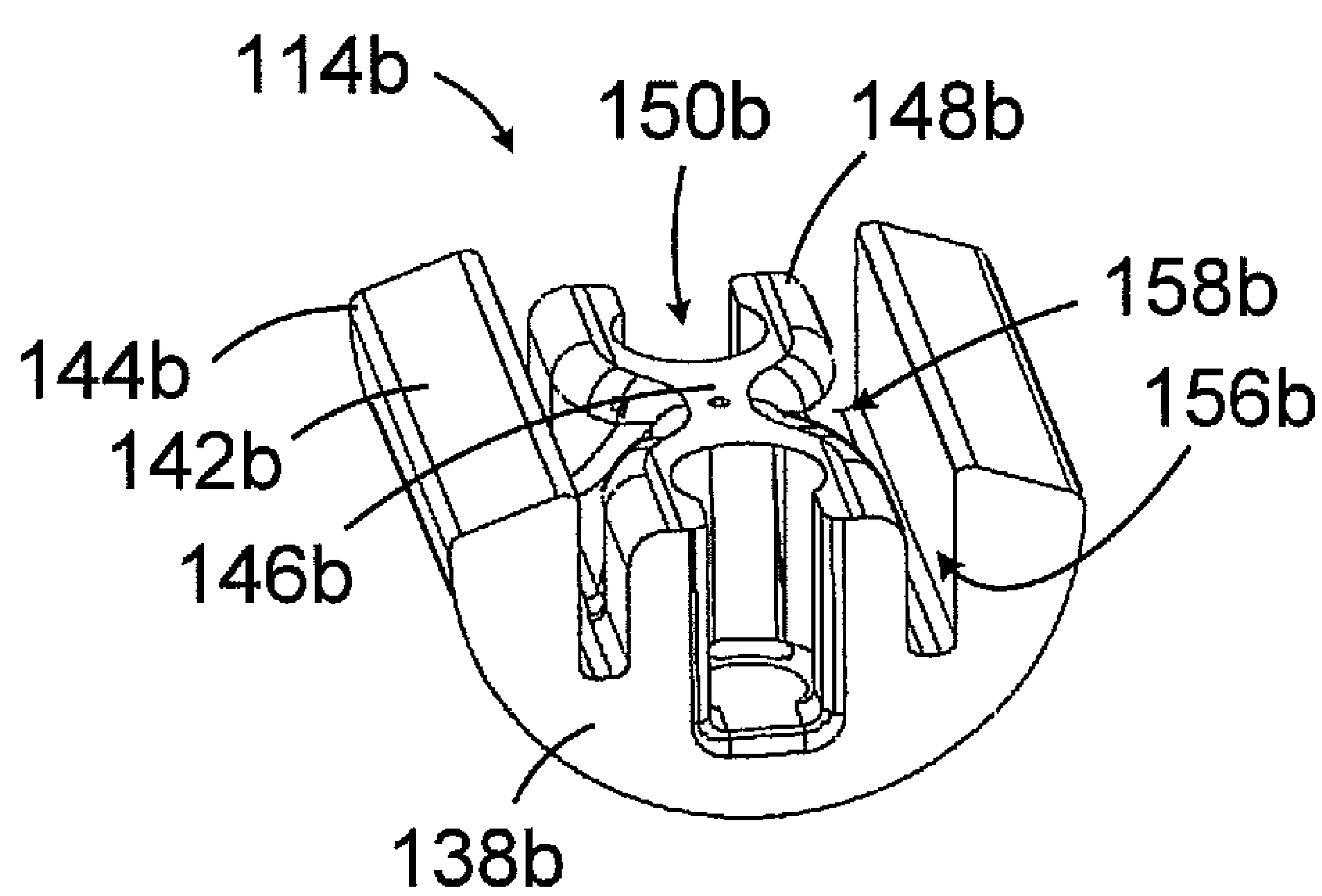

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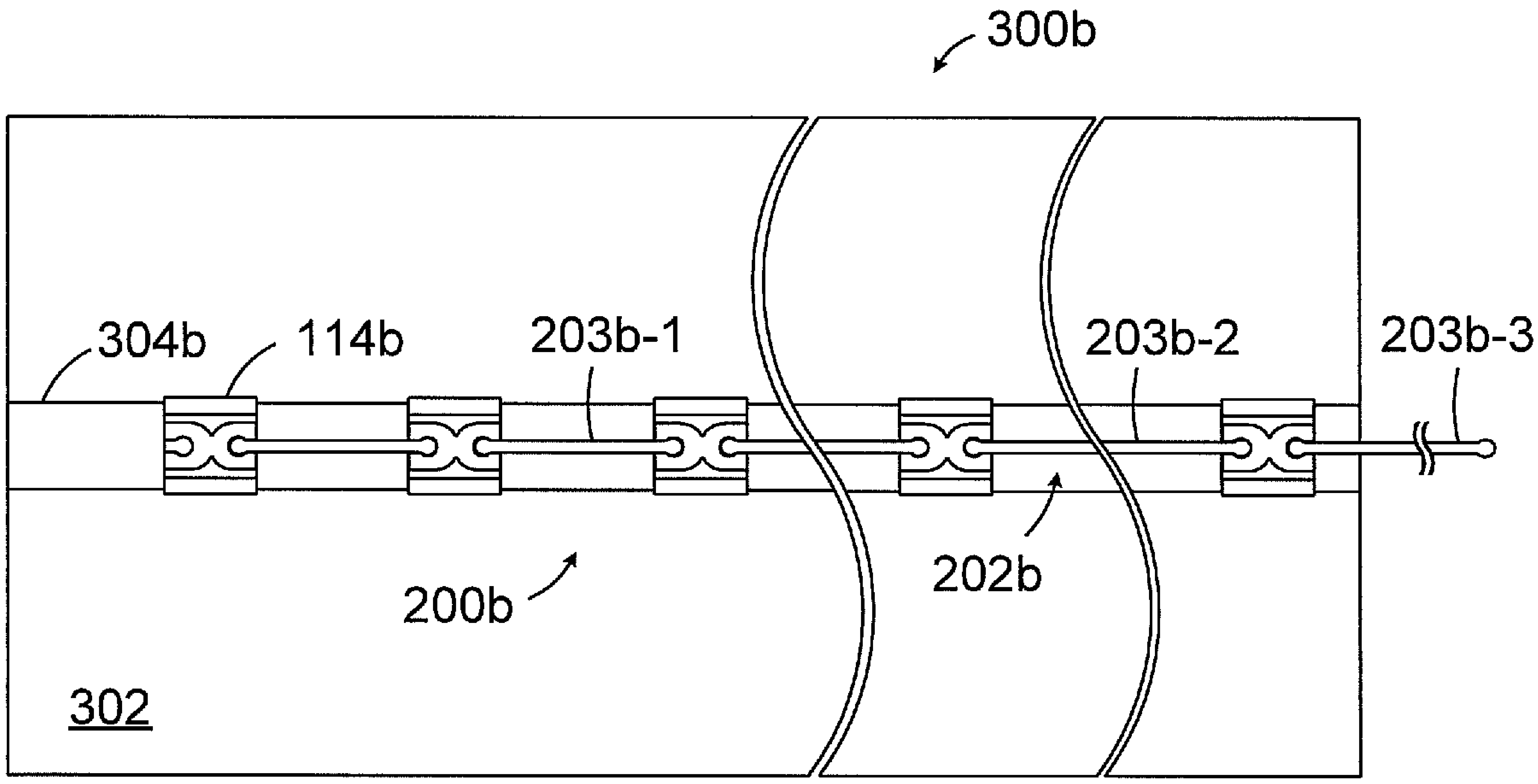

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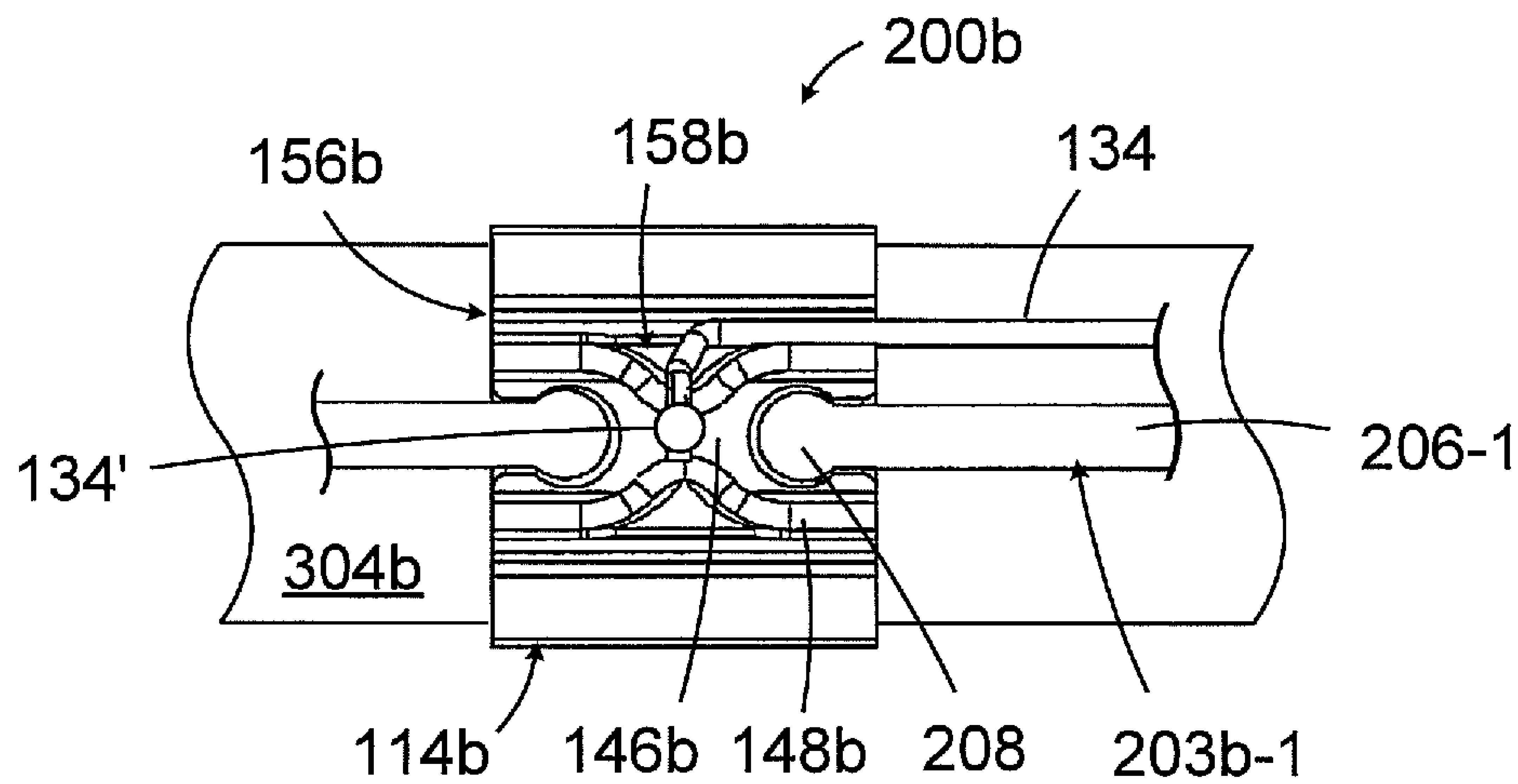

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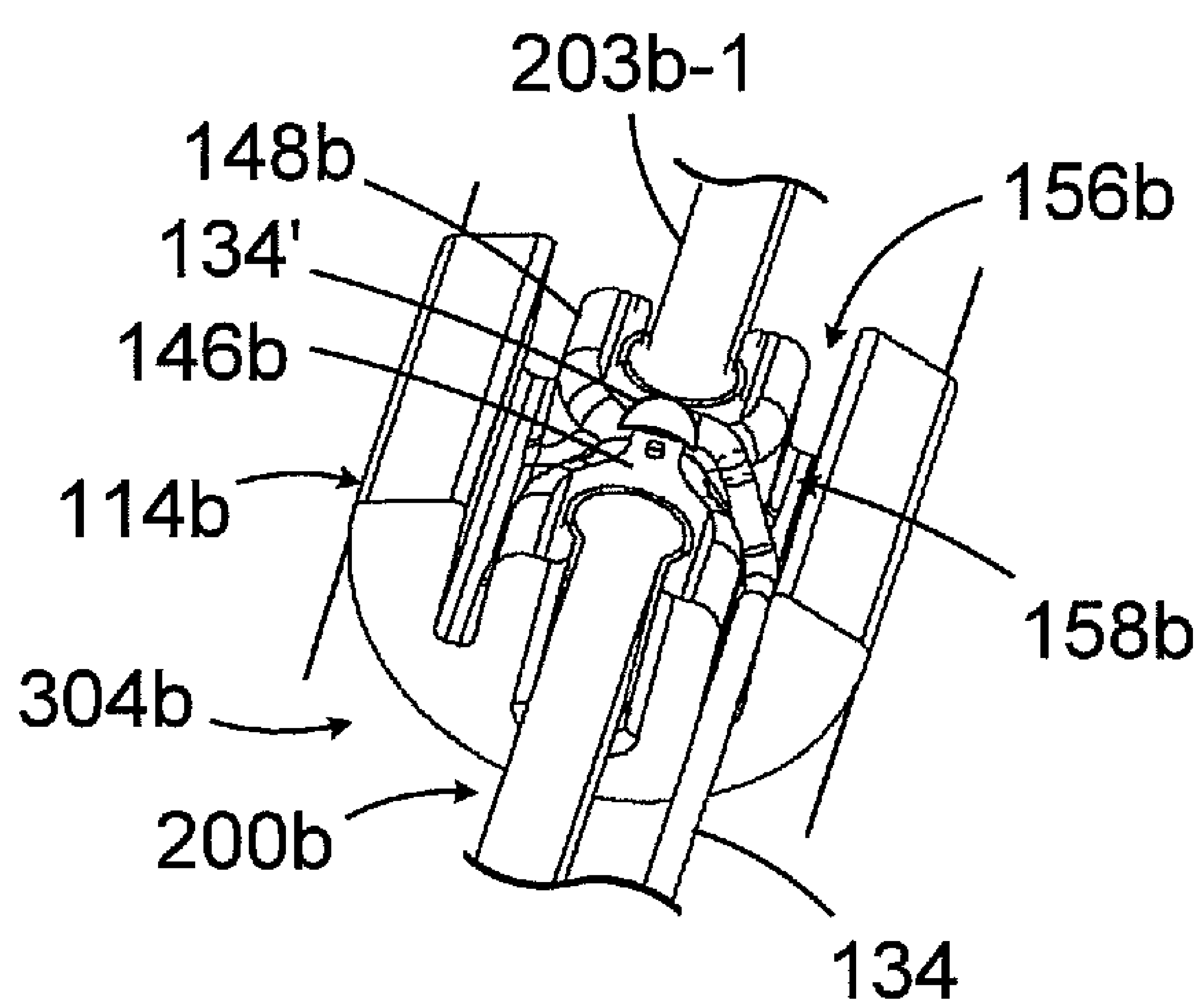

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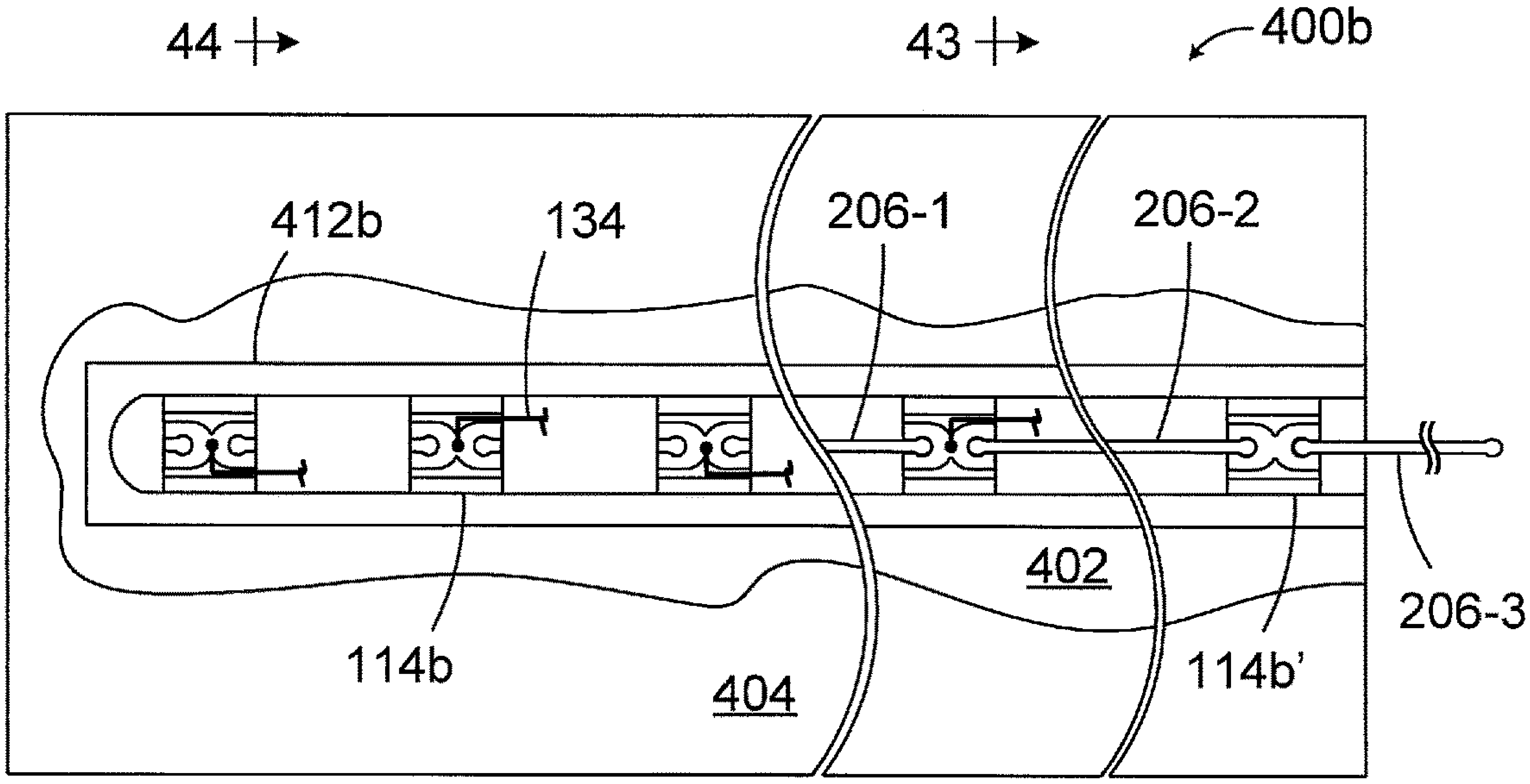

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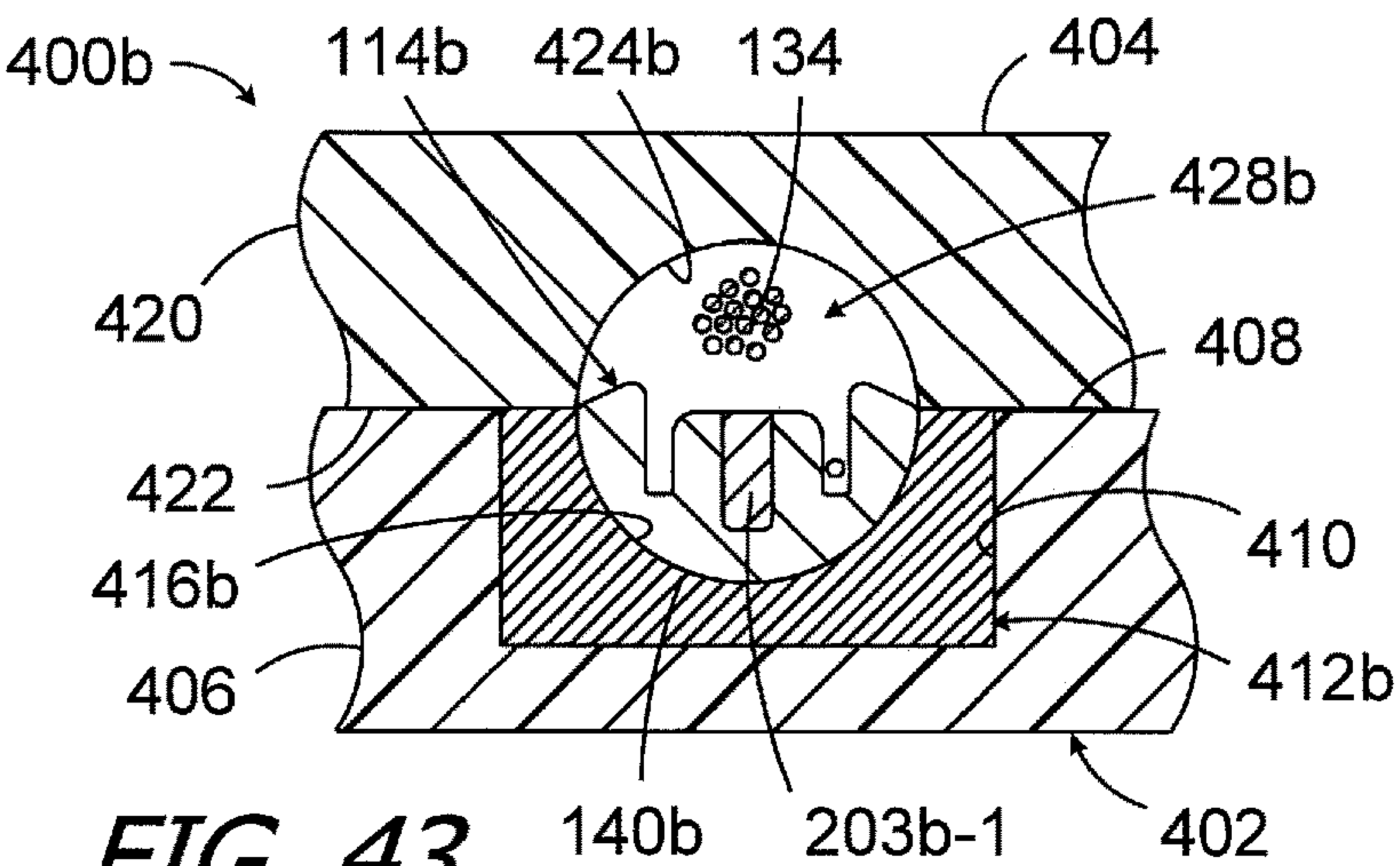

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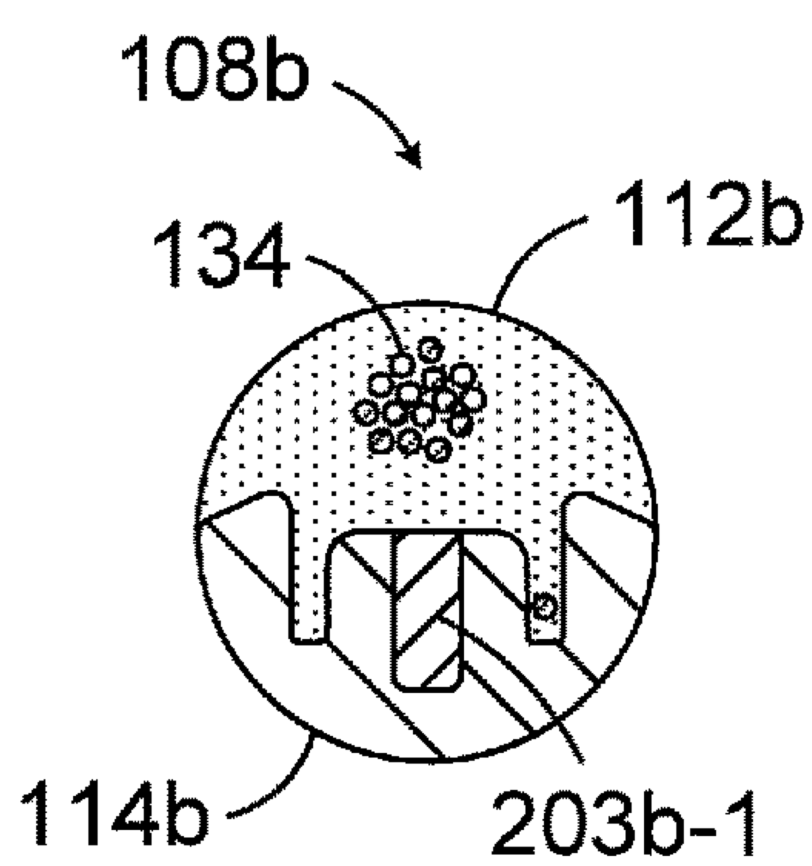

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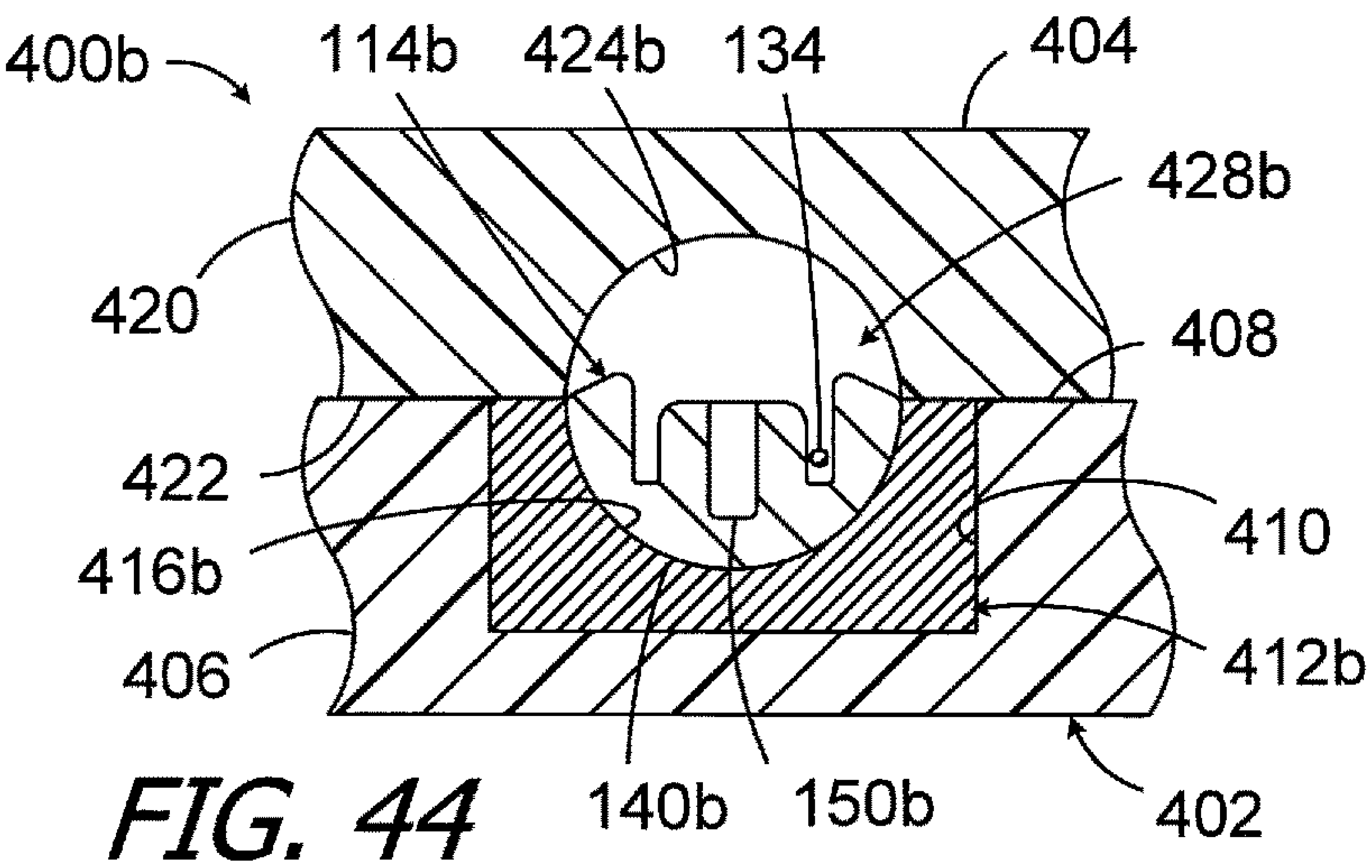

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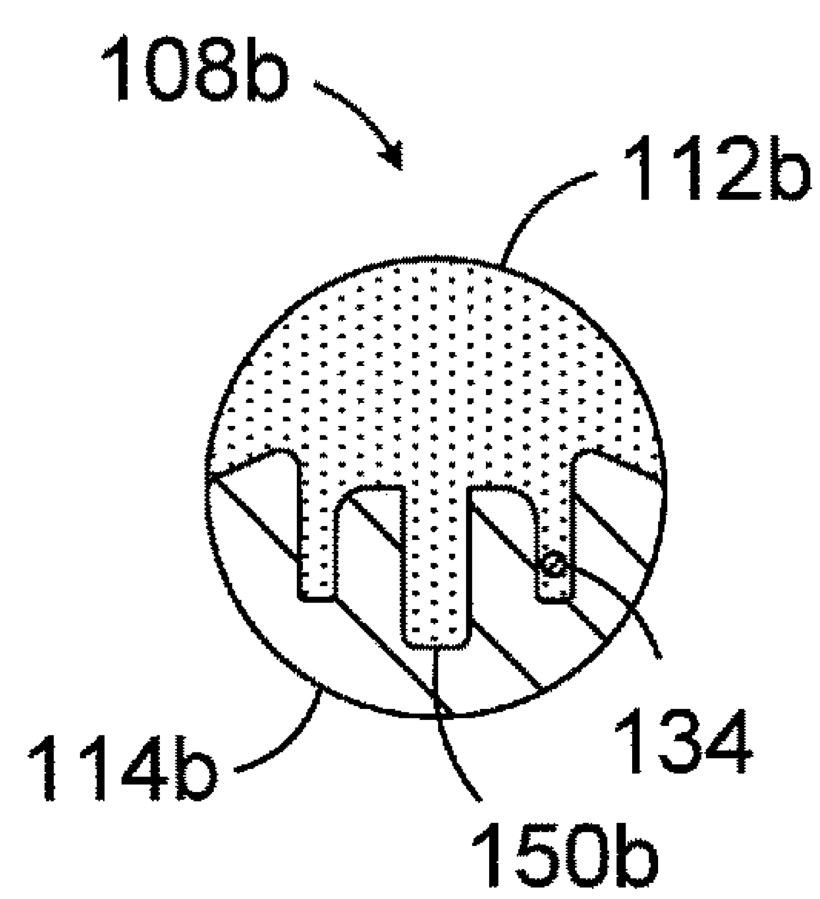

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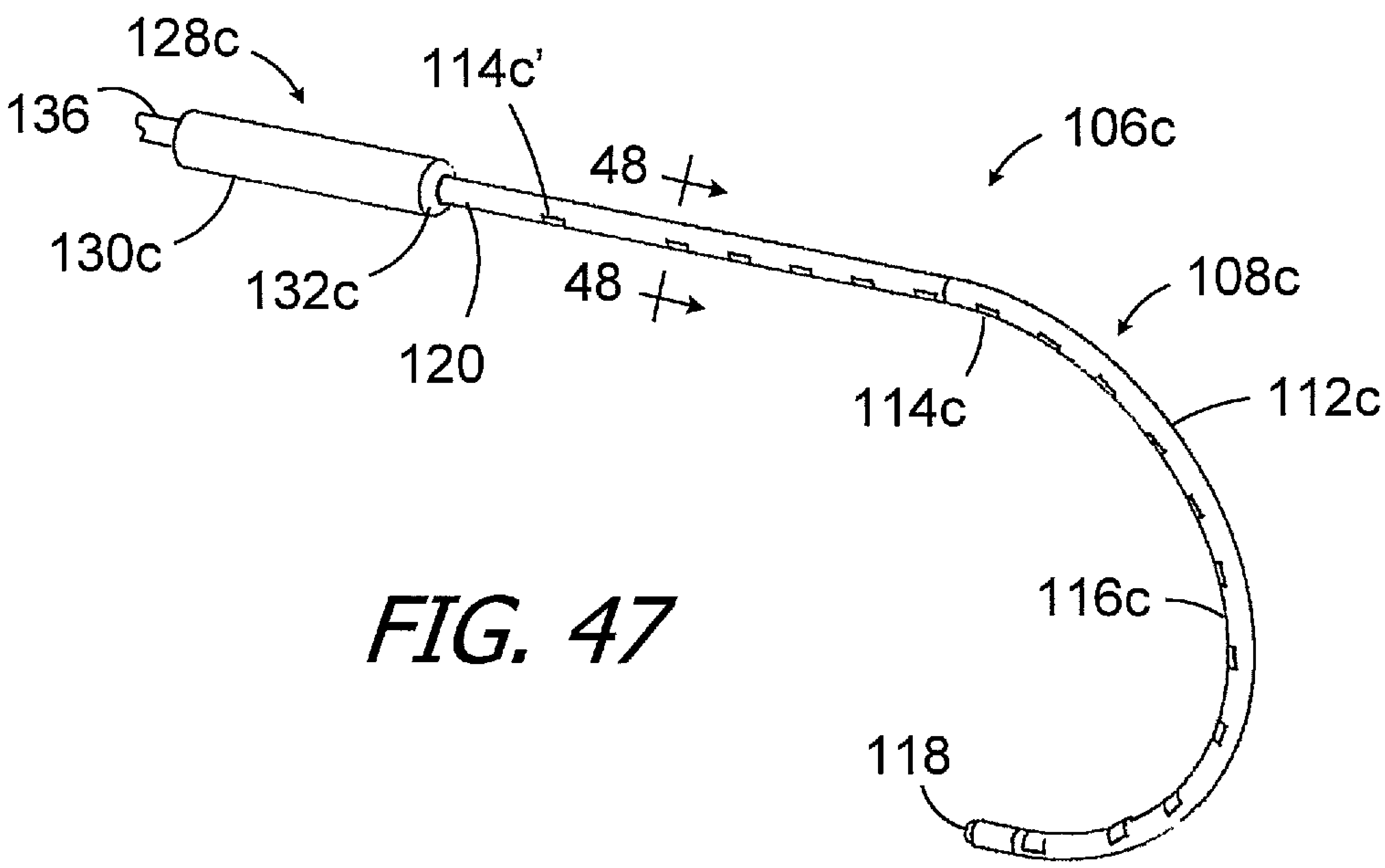

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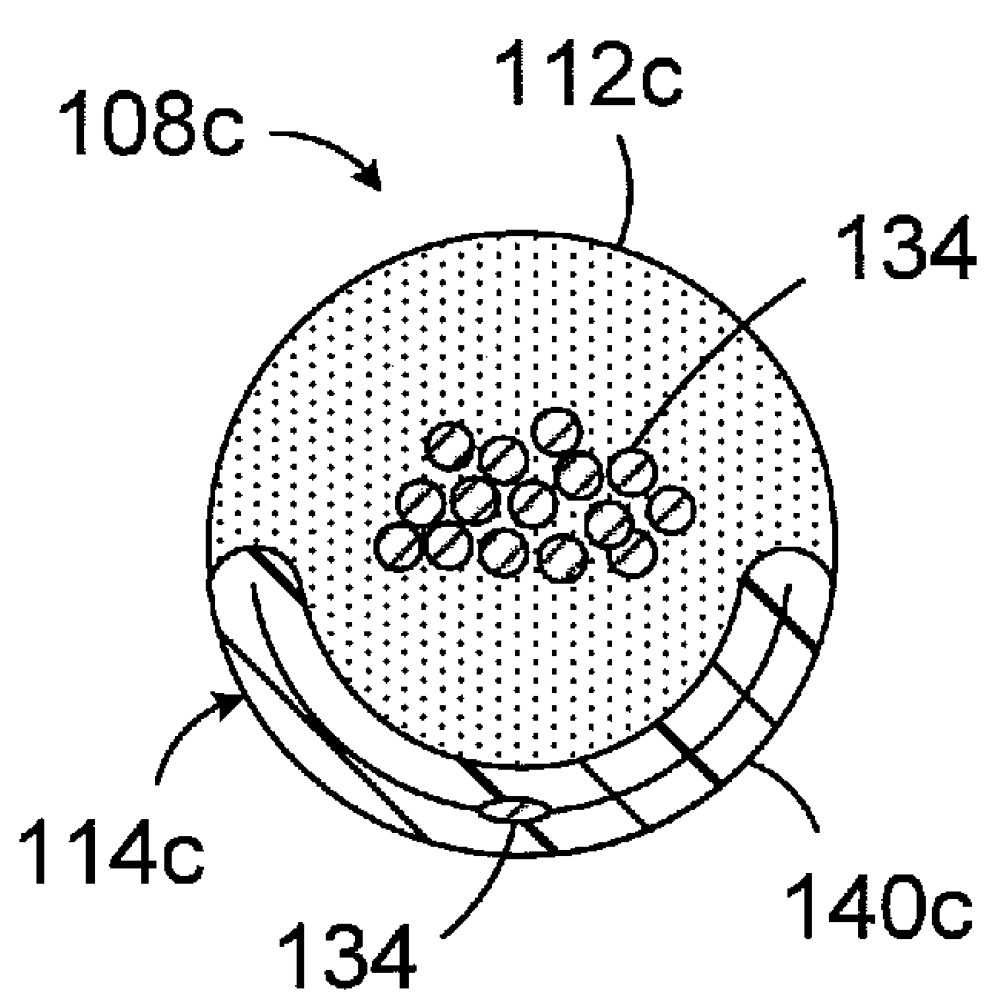

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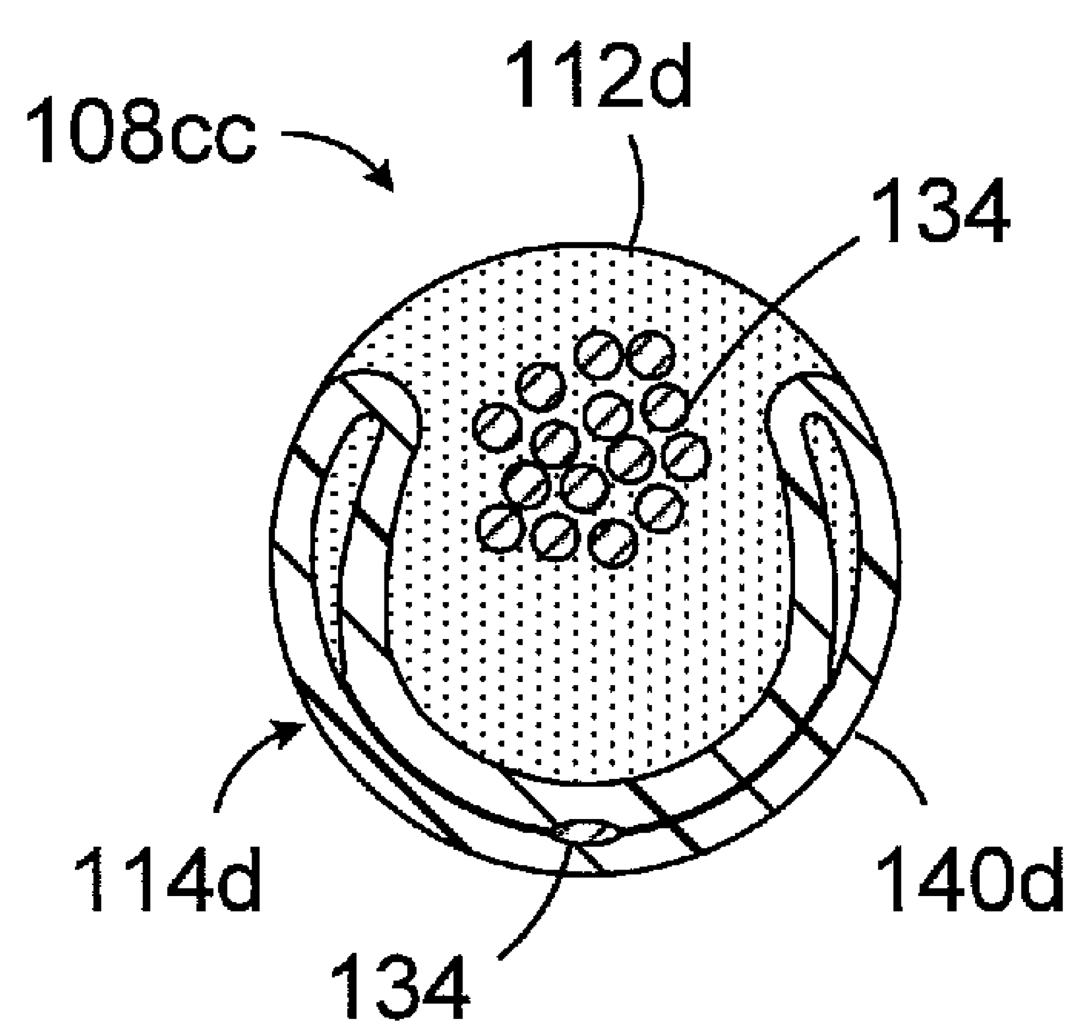


FIG. 49

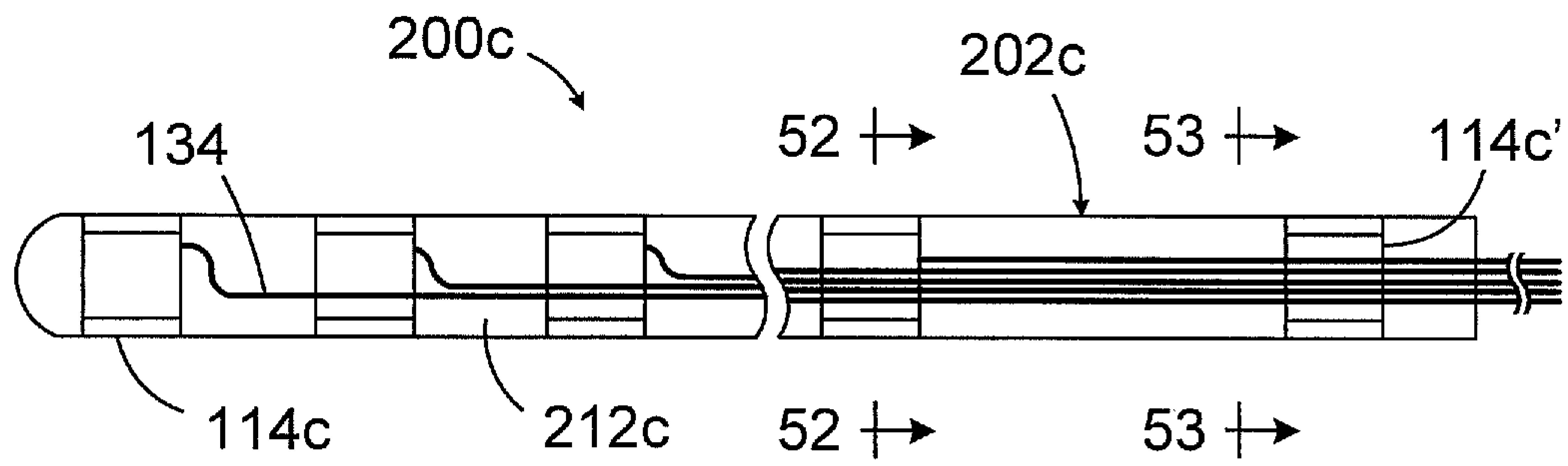


FIG. 50

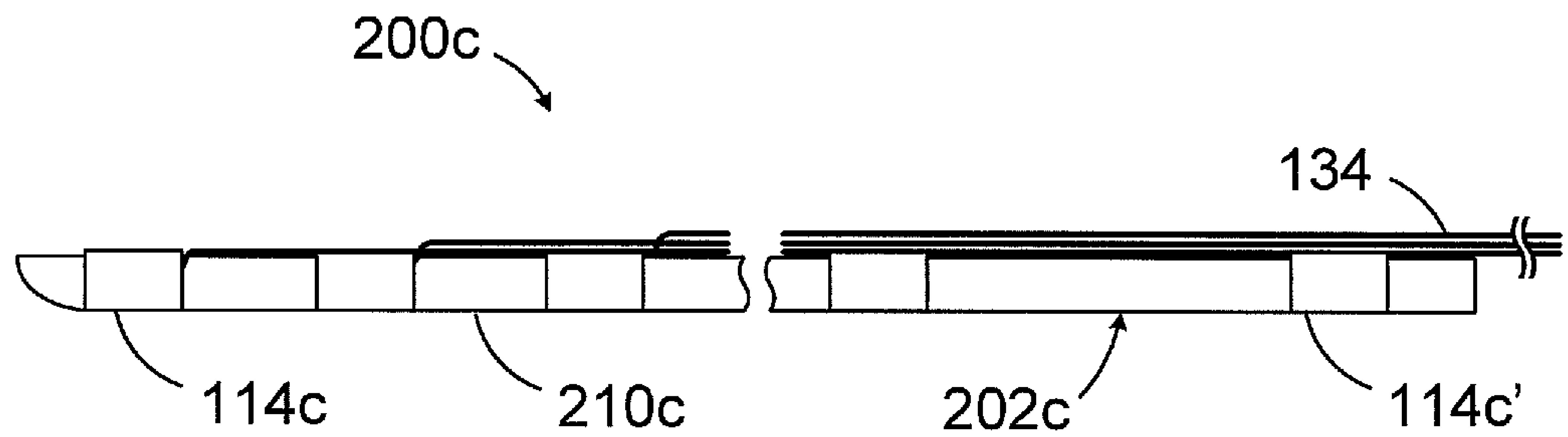


FIG. 51

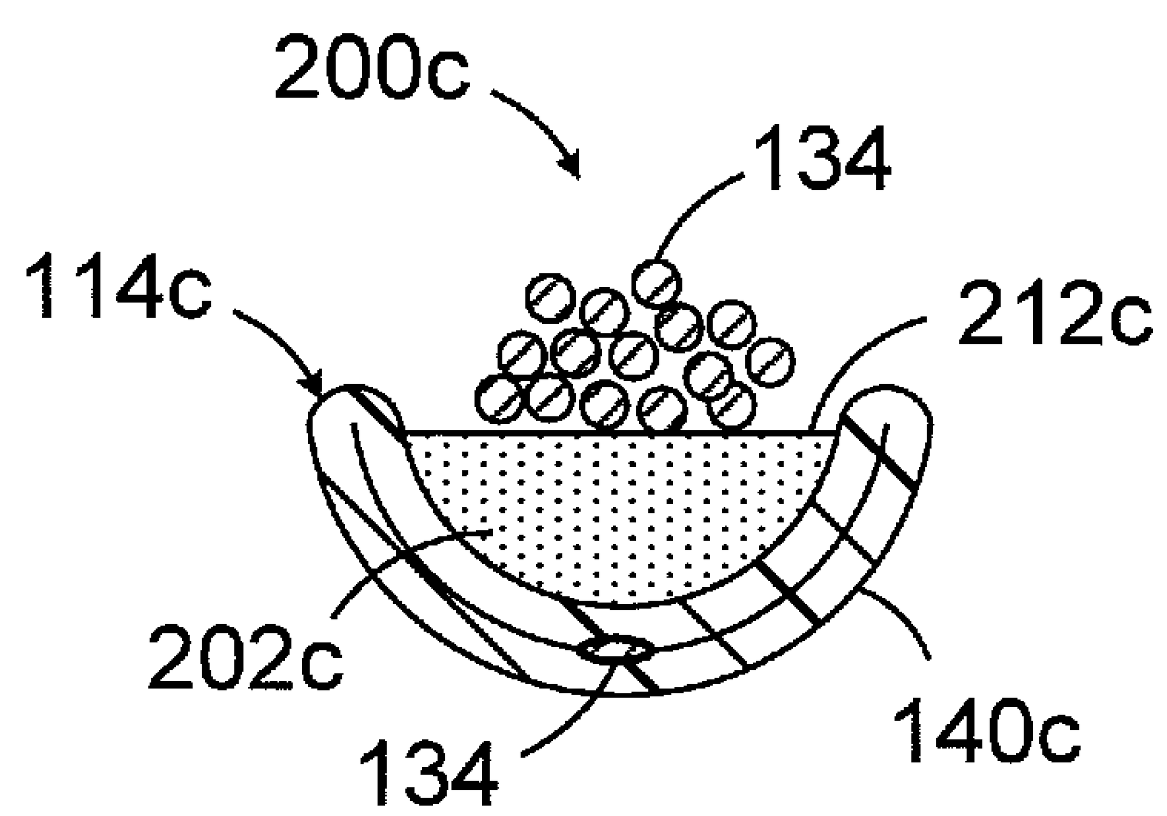
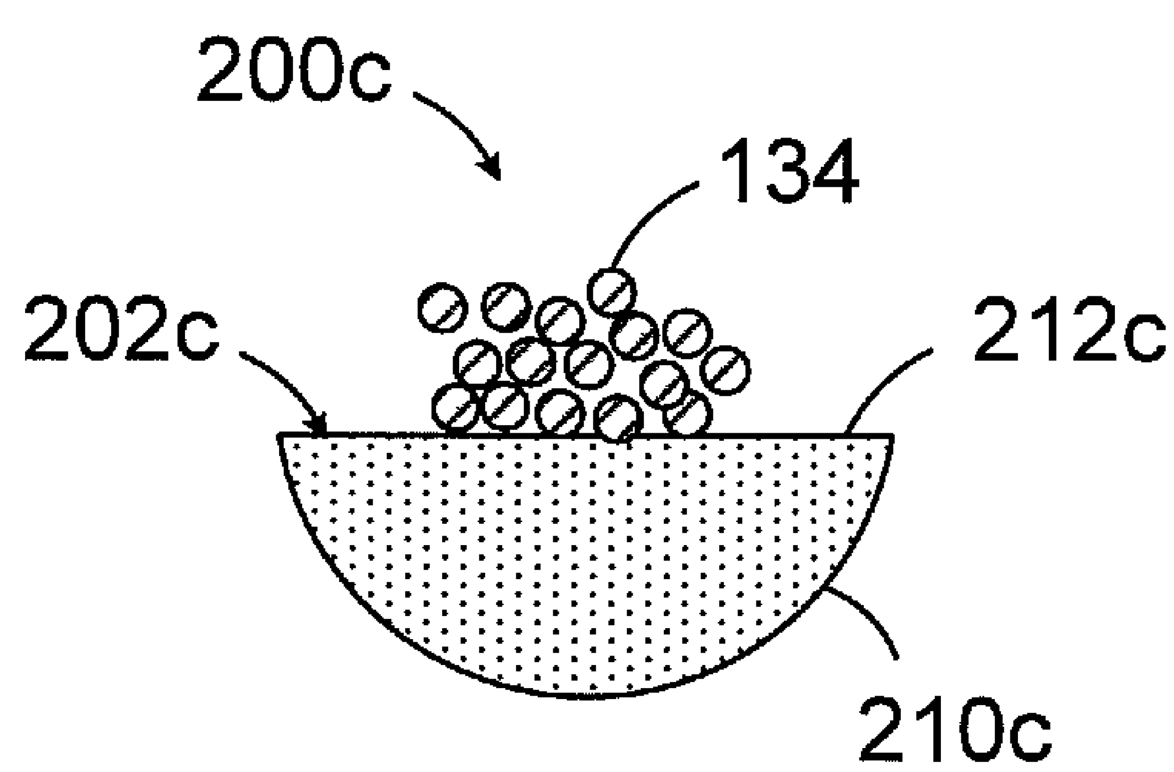


FIG. 52



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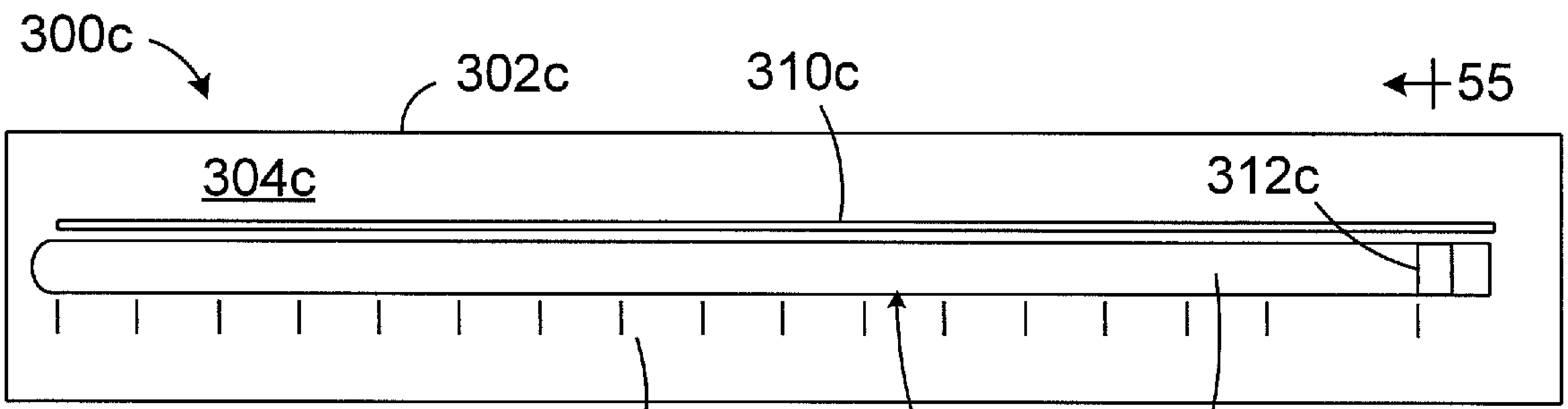

FIG. 54

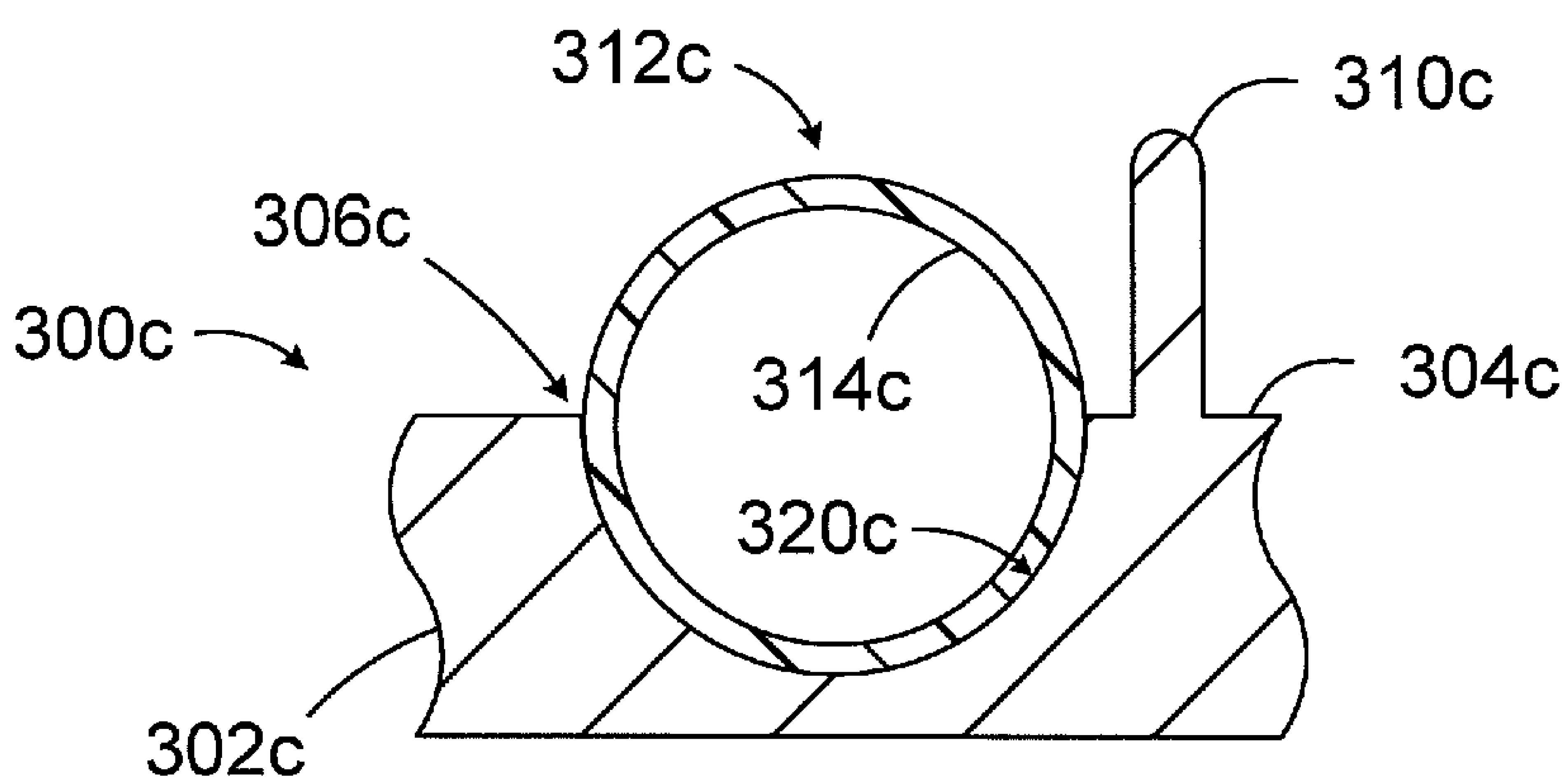

FIG. 55

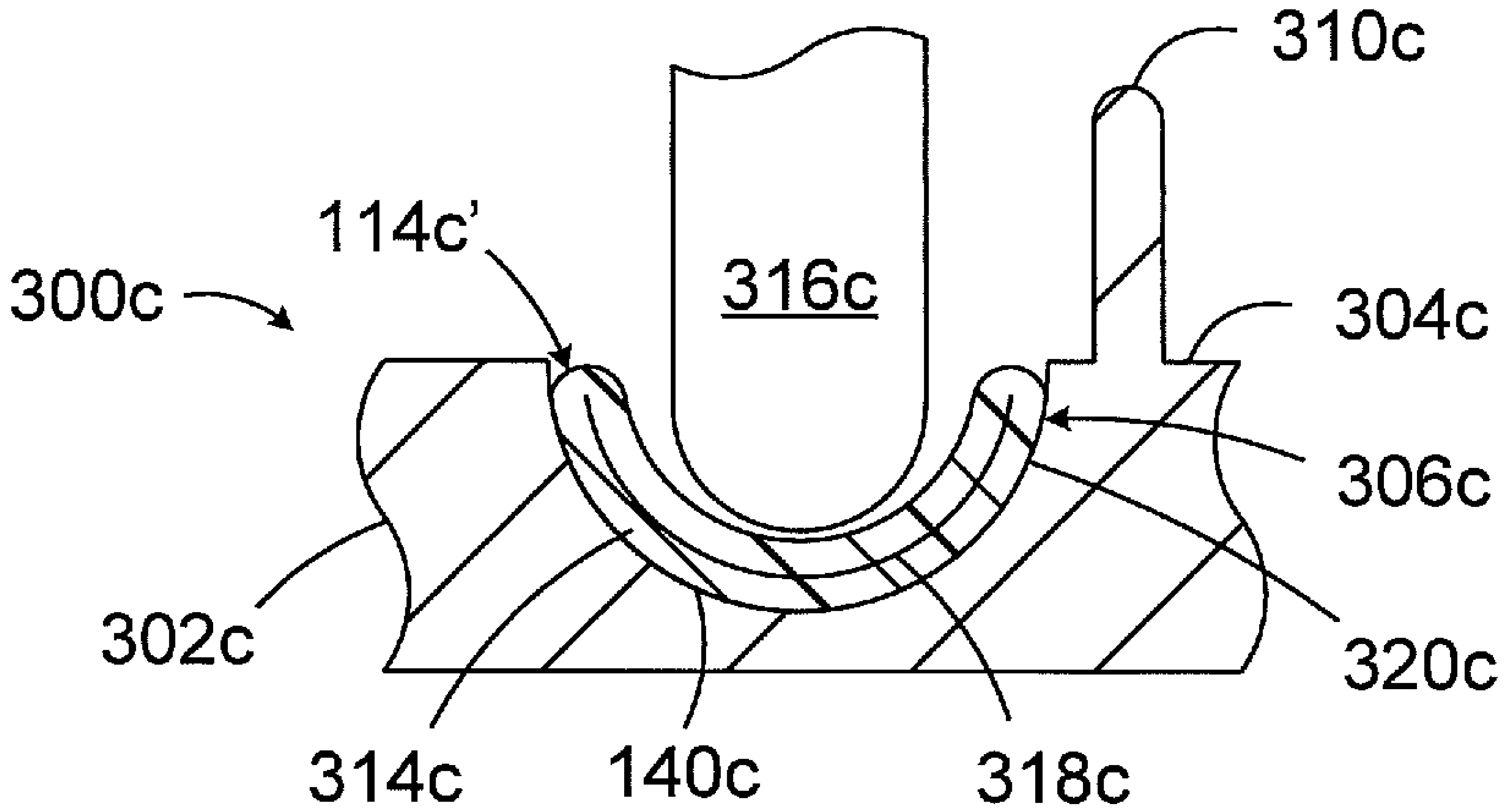

FIG. 56

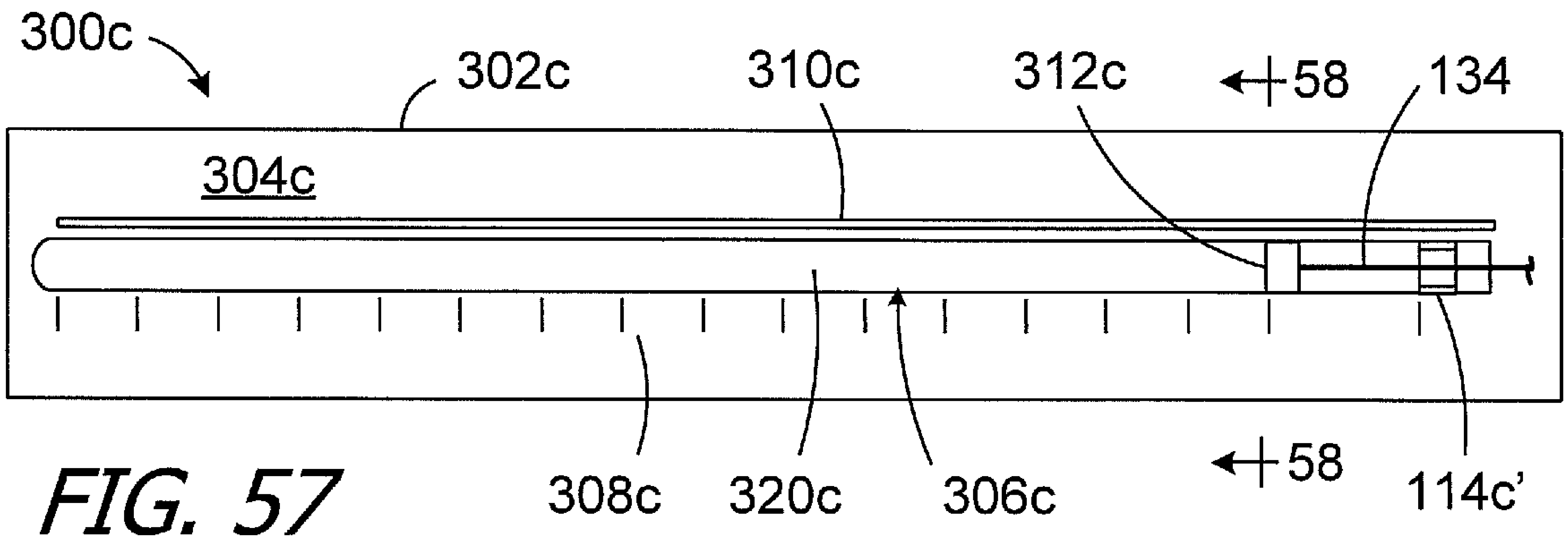

FIG. 57

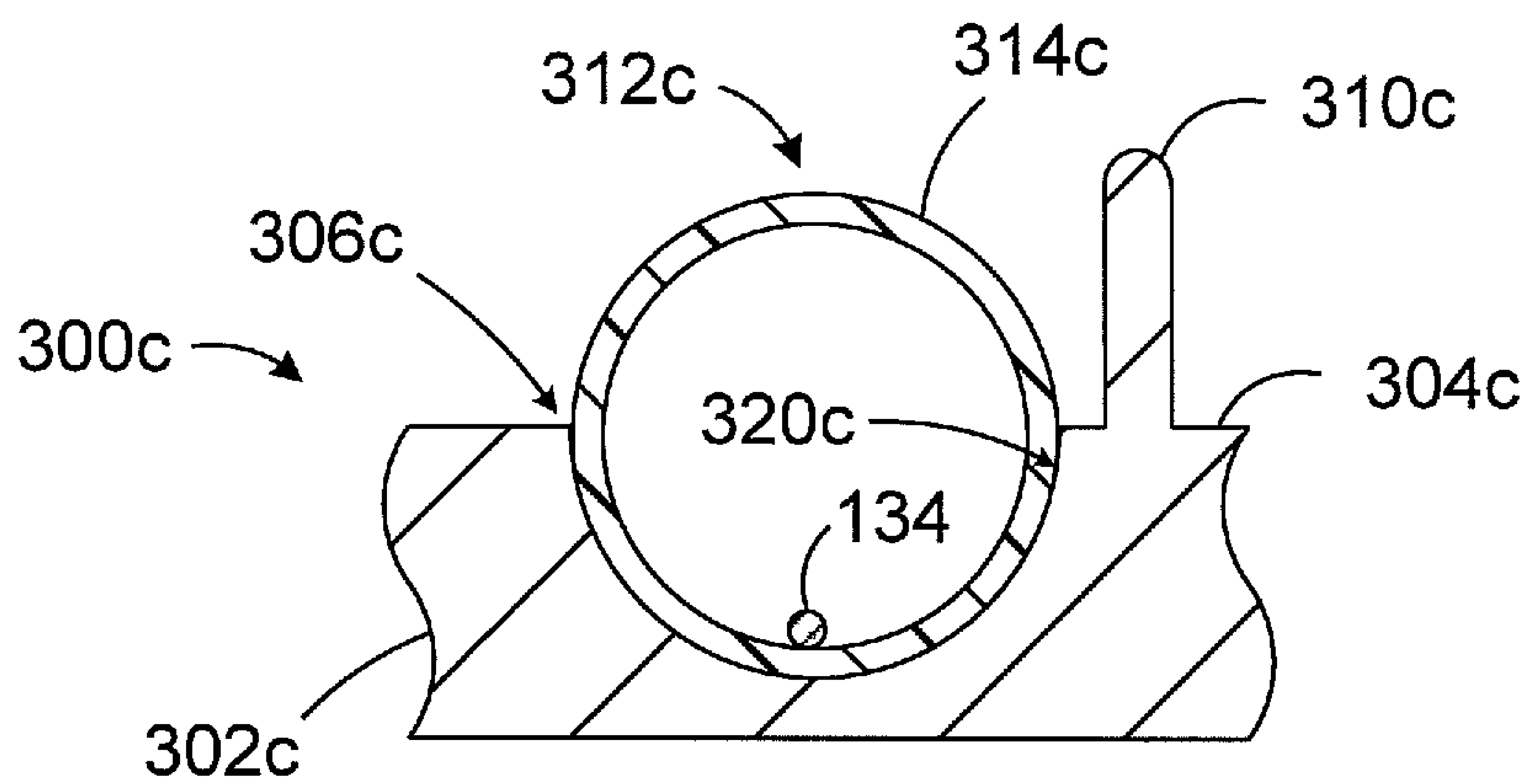

FIG. 58

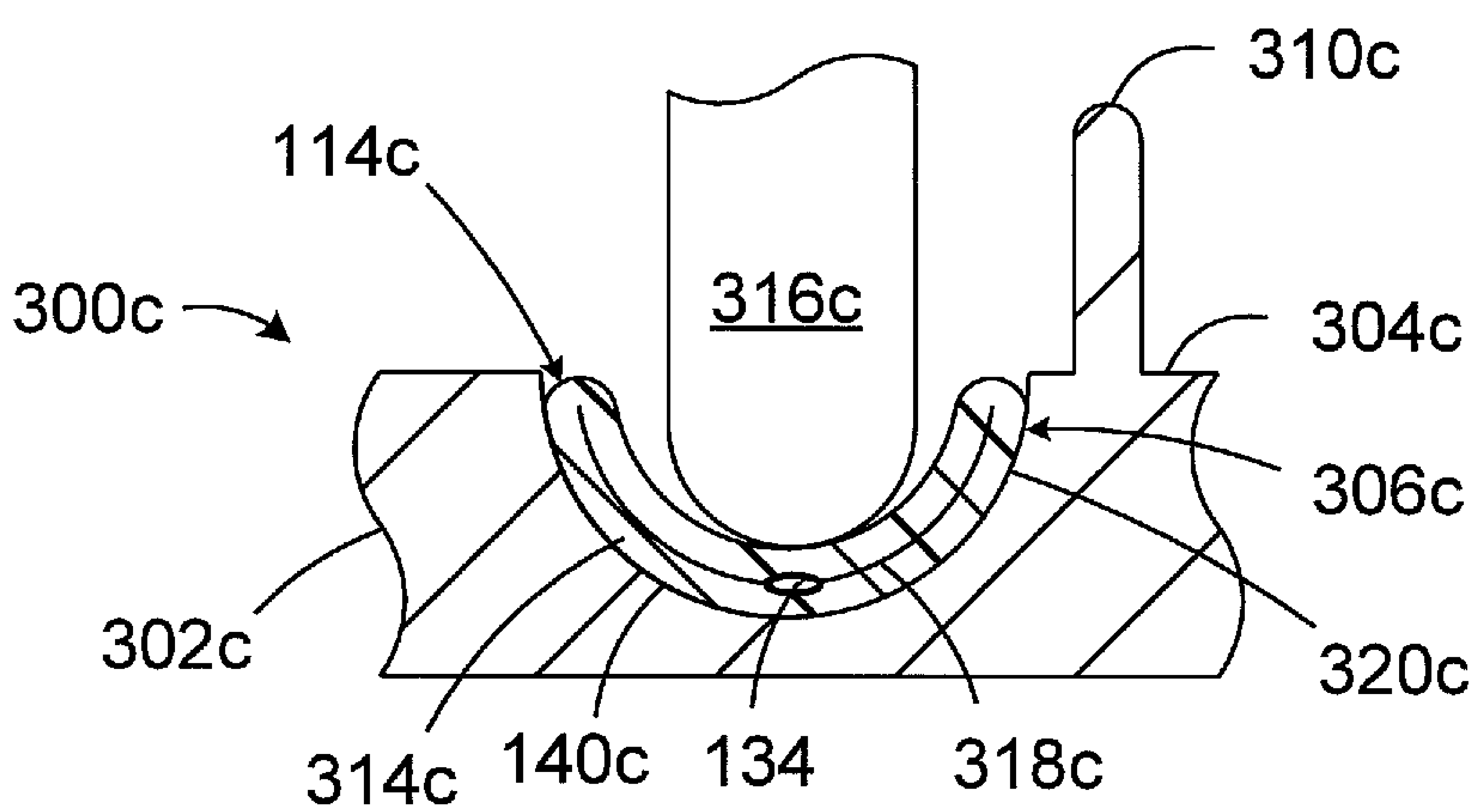

FIG. 59

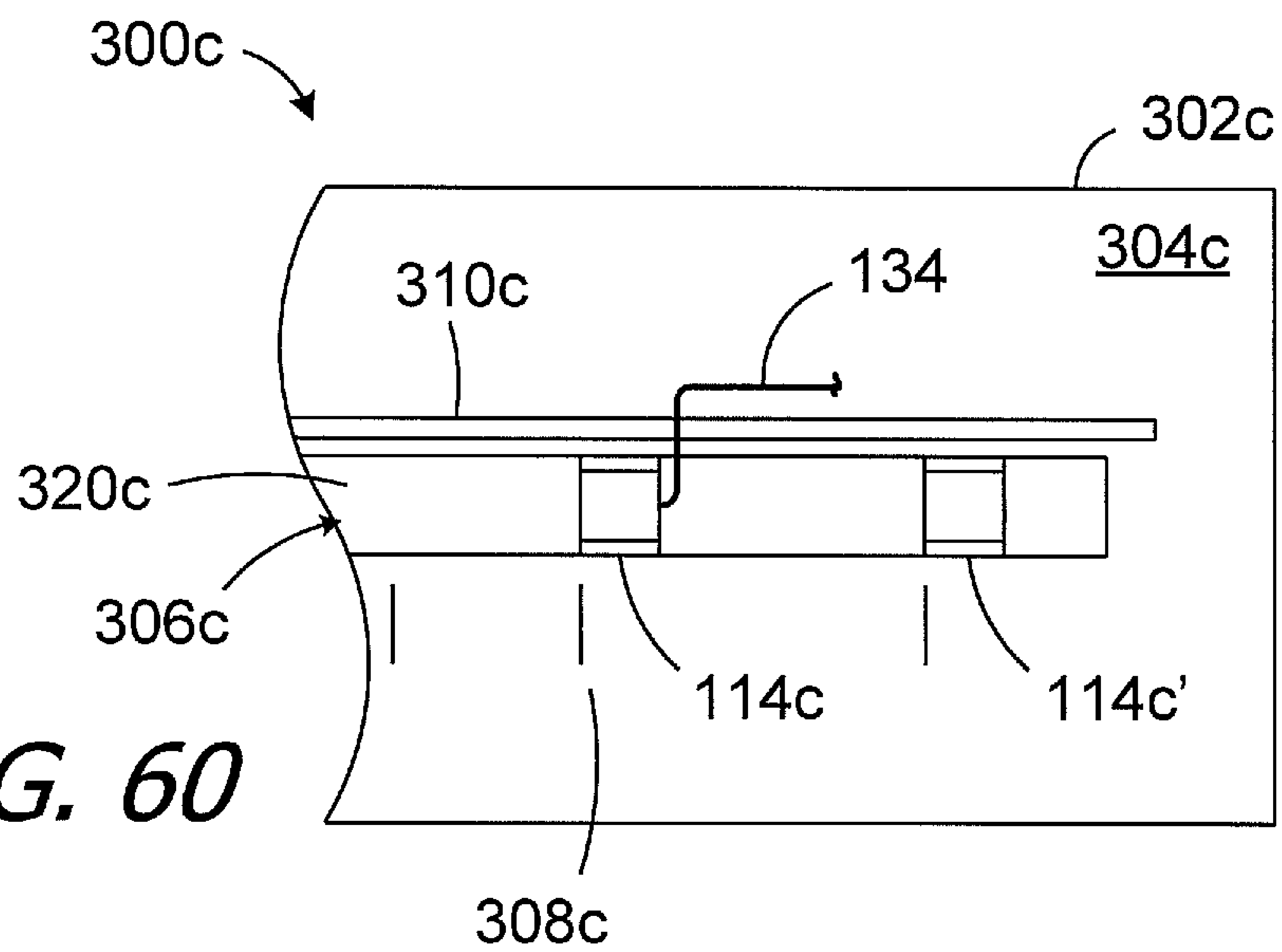

FIG. 60

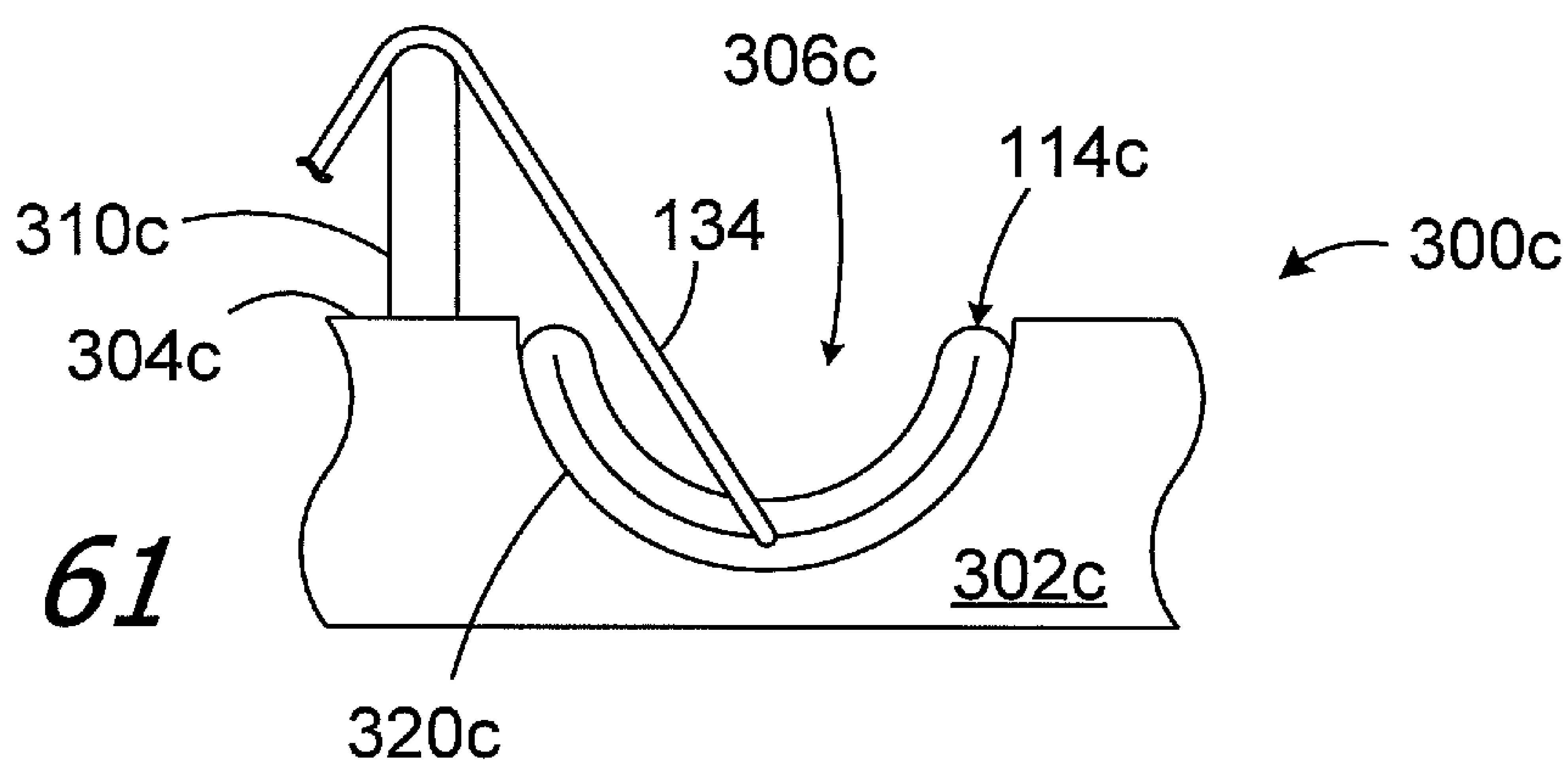

FIG. 61

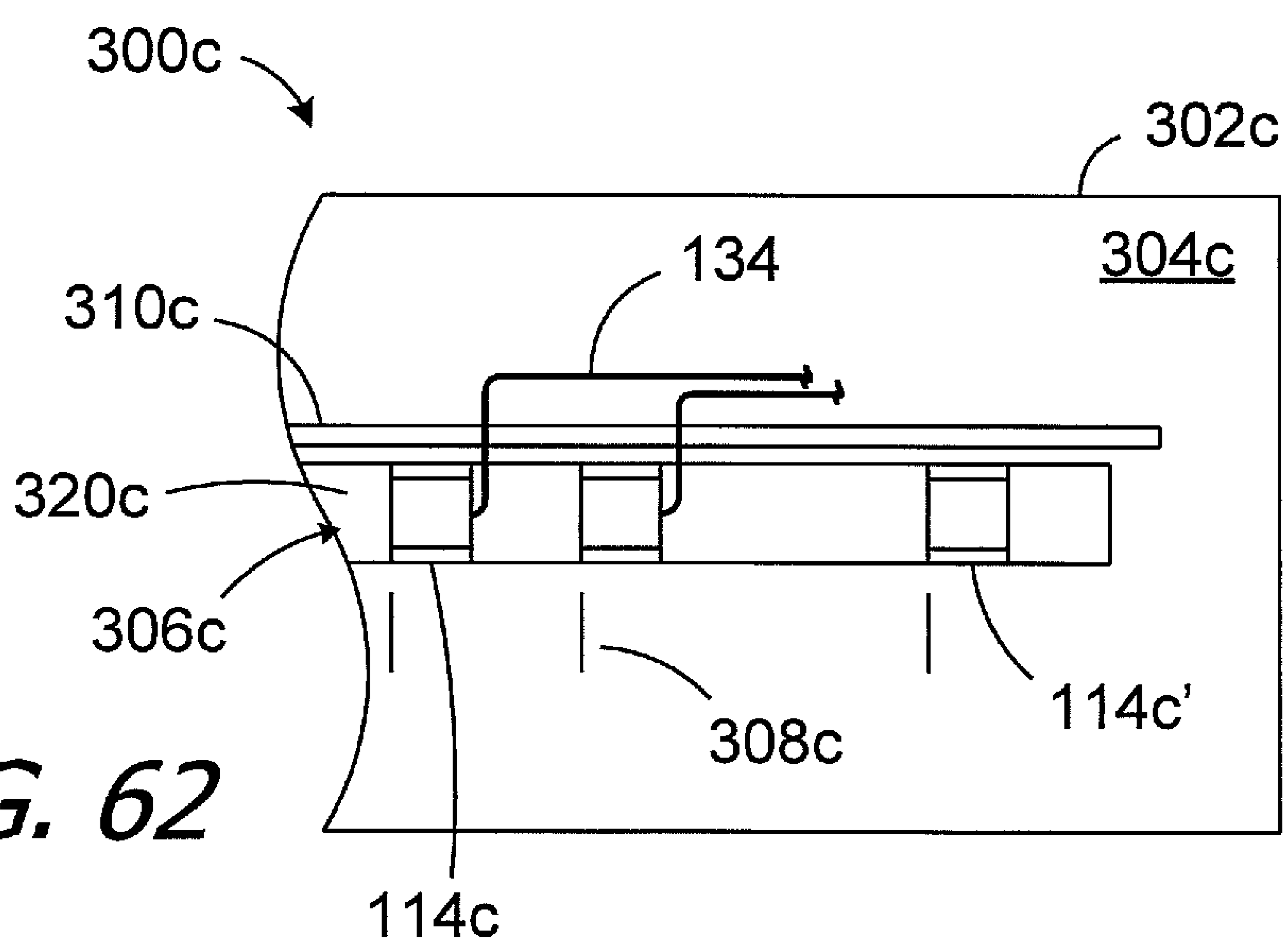

FIG. 62

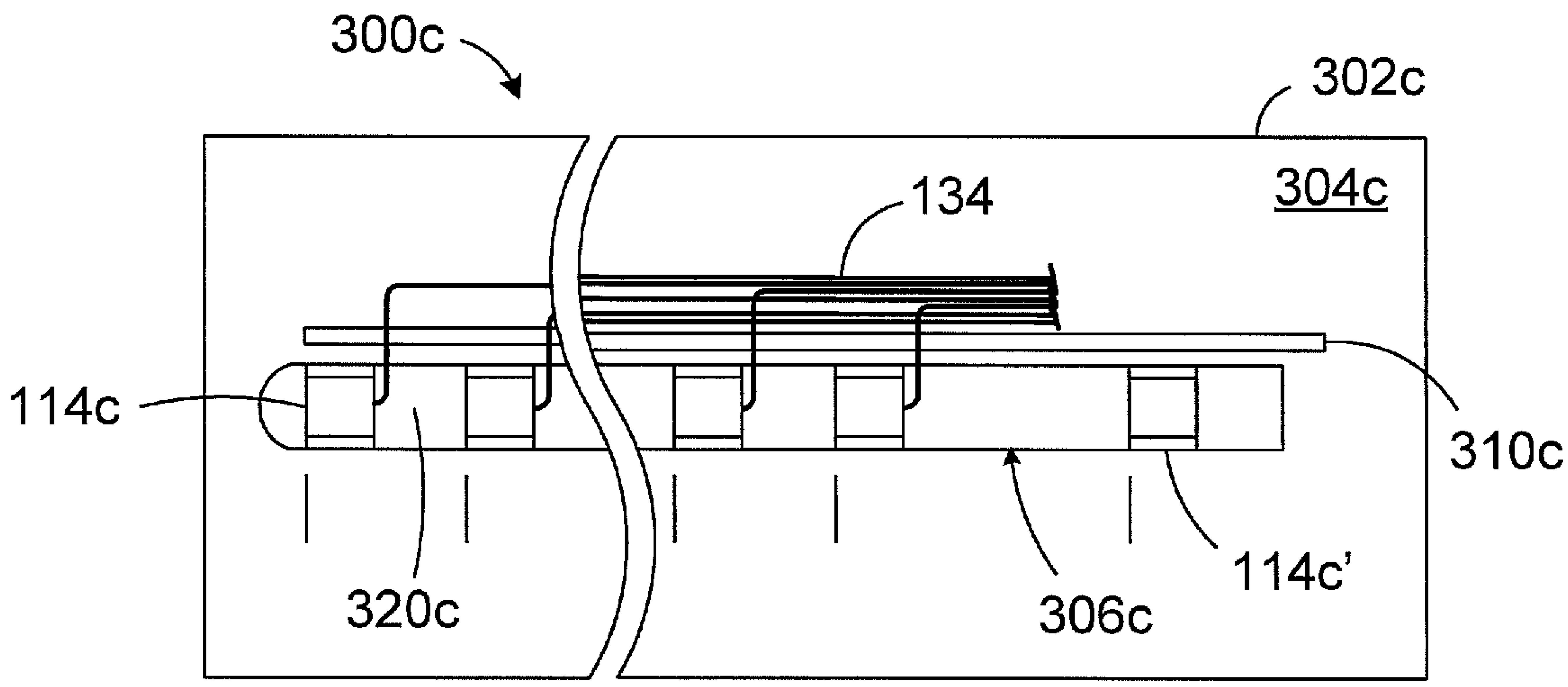

FIG. 63

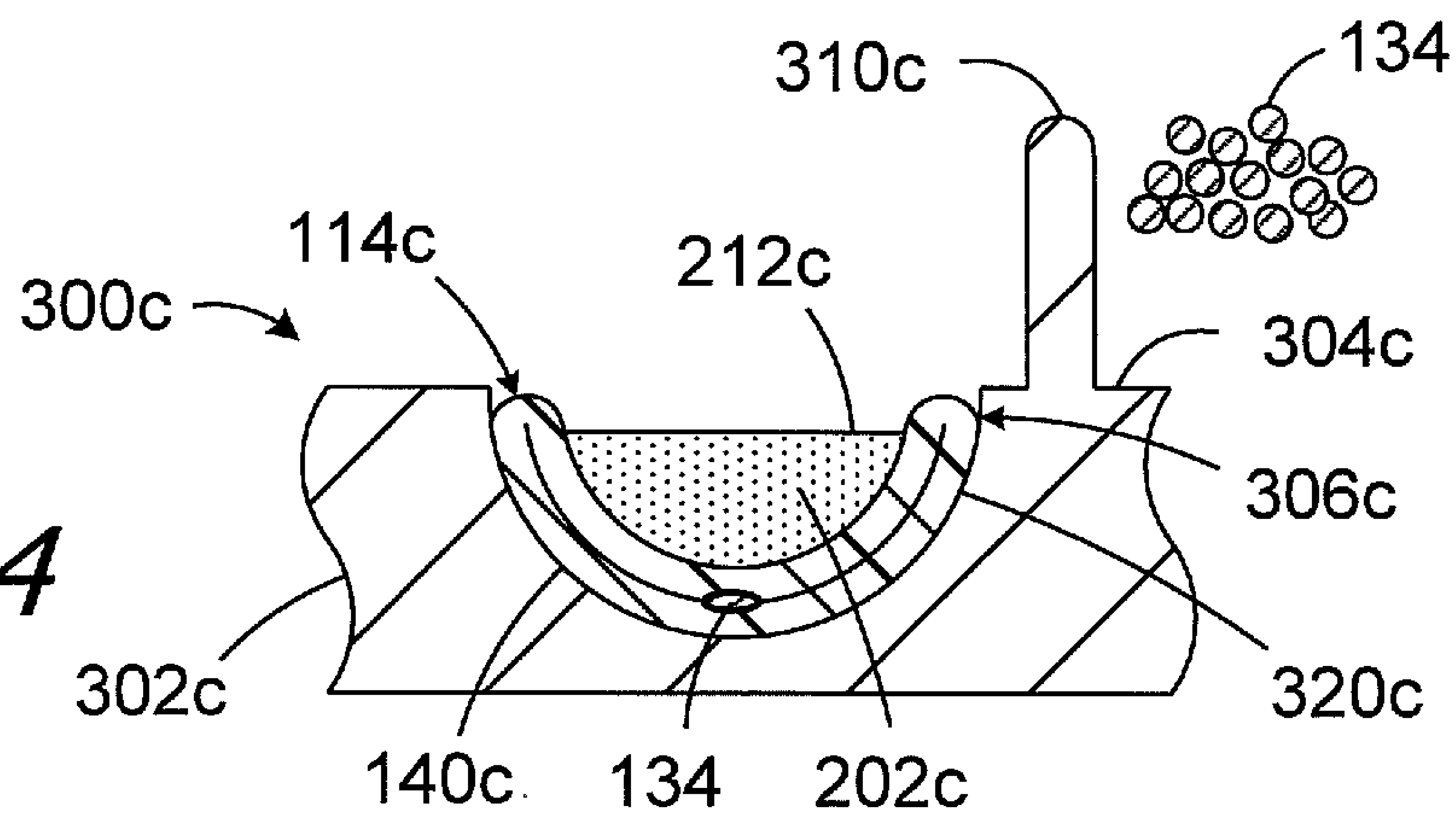

FIG. 64

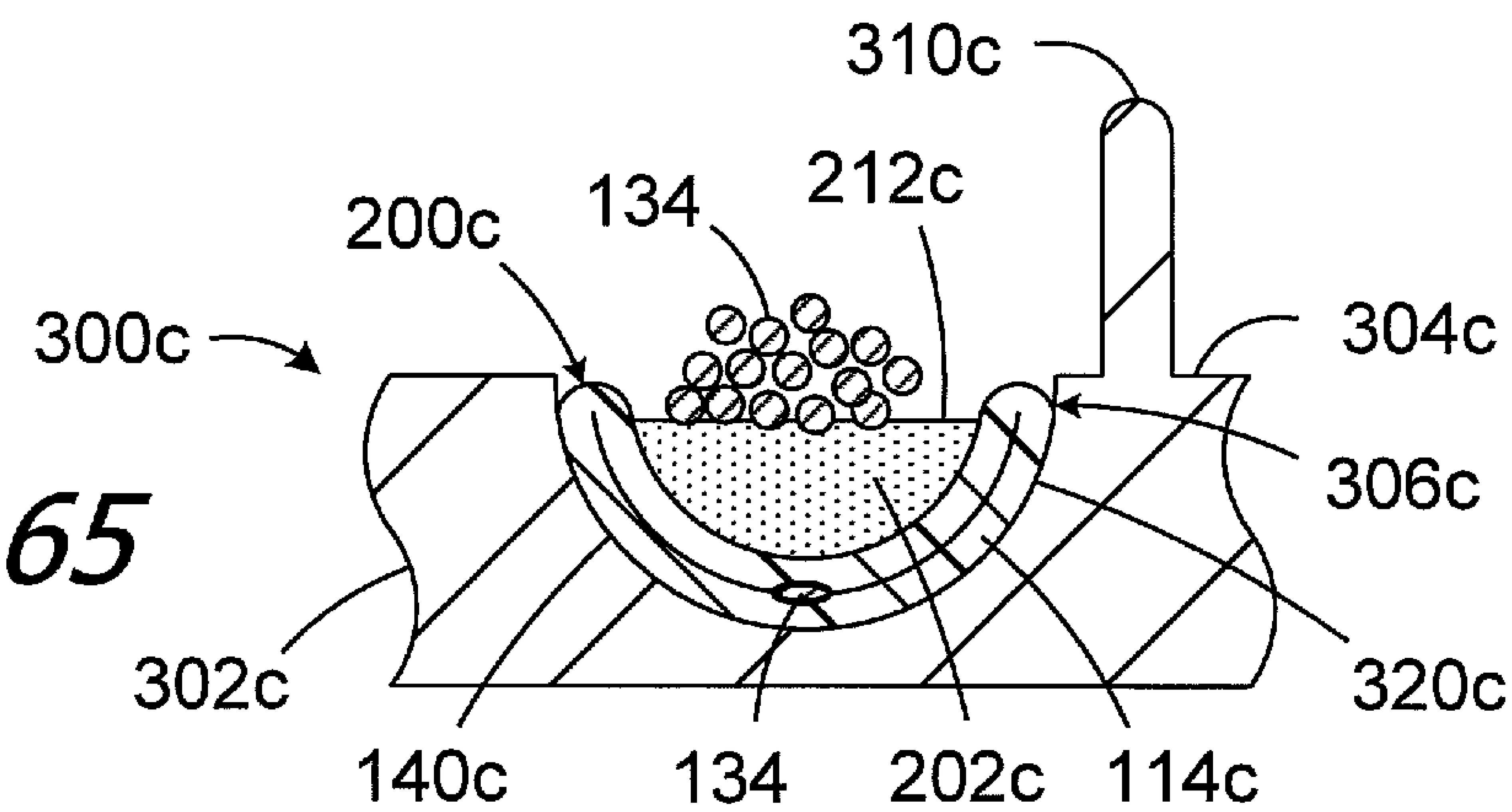

FIG. 65

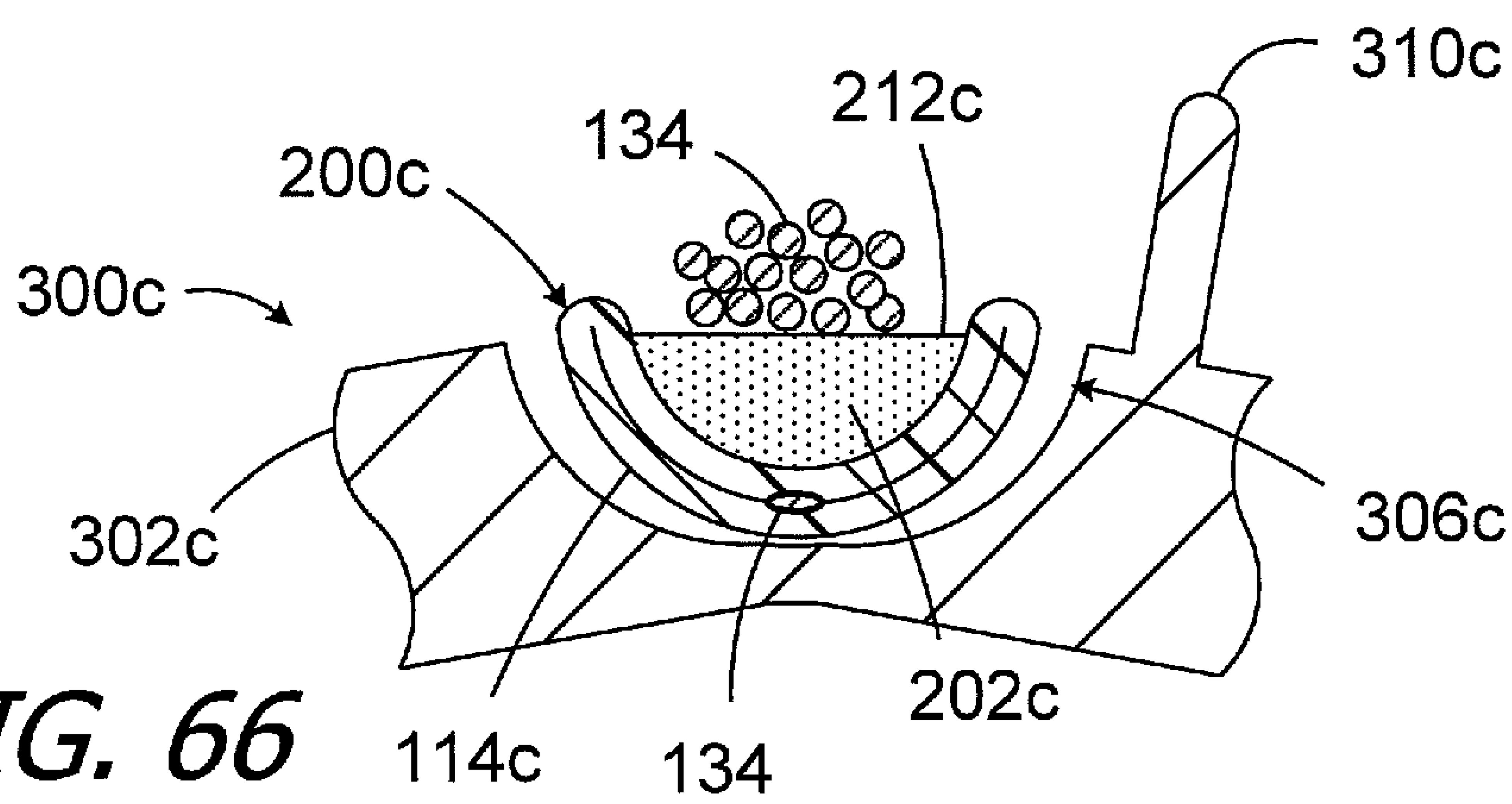

FIG. 66

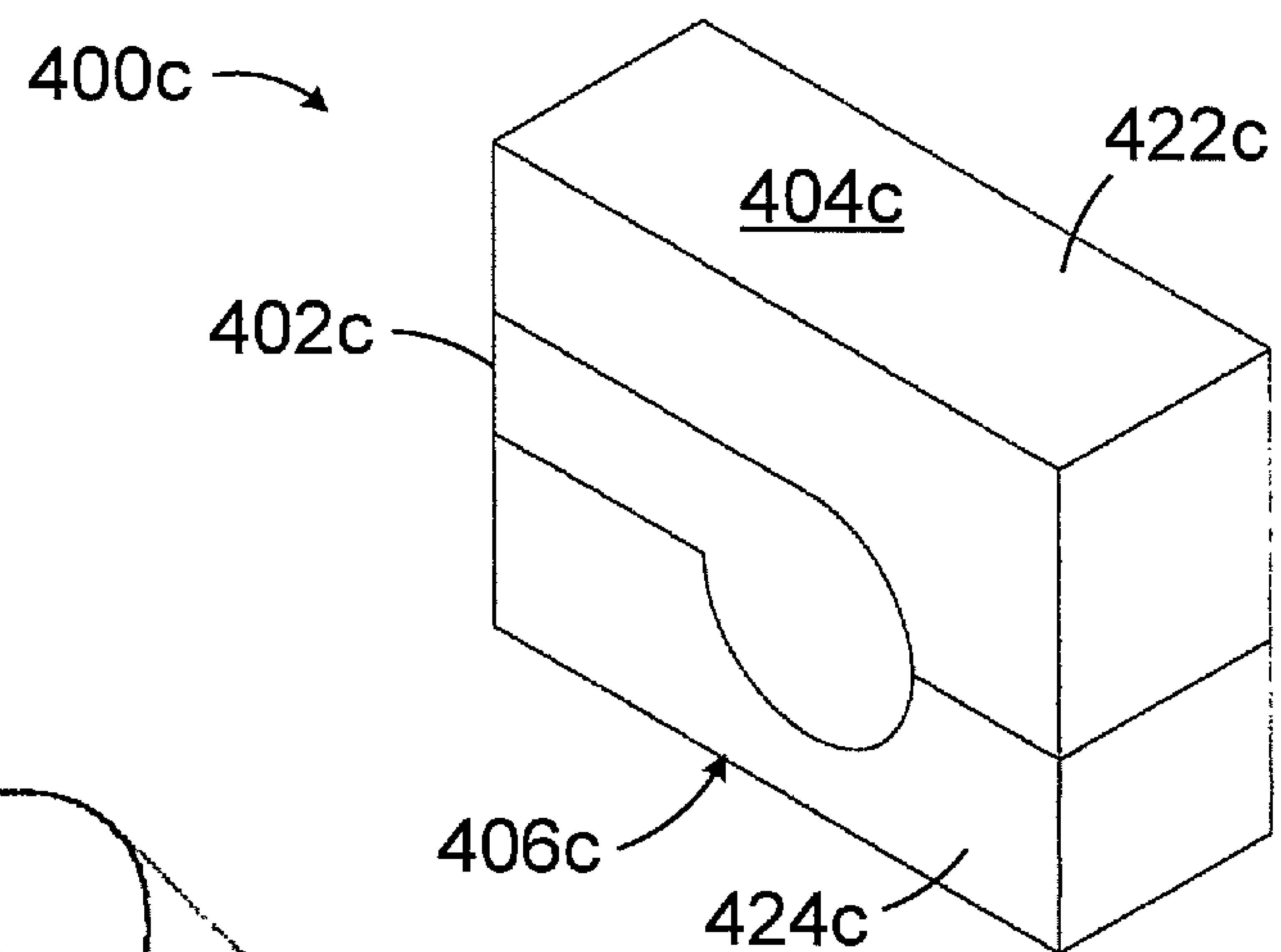

FIG. 67

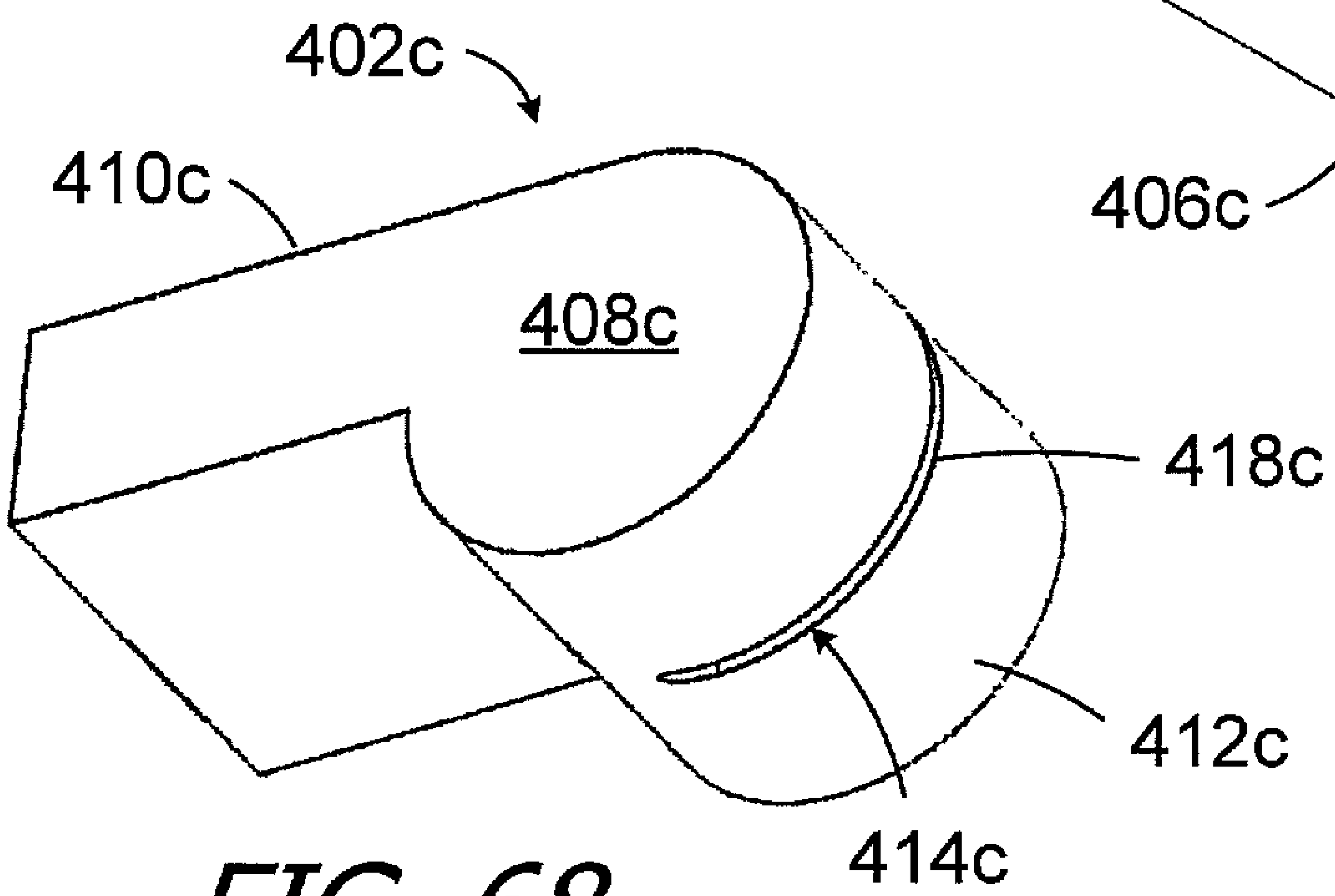

FIG. 68

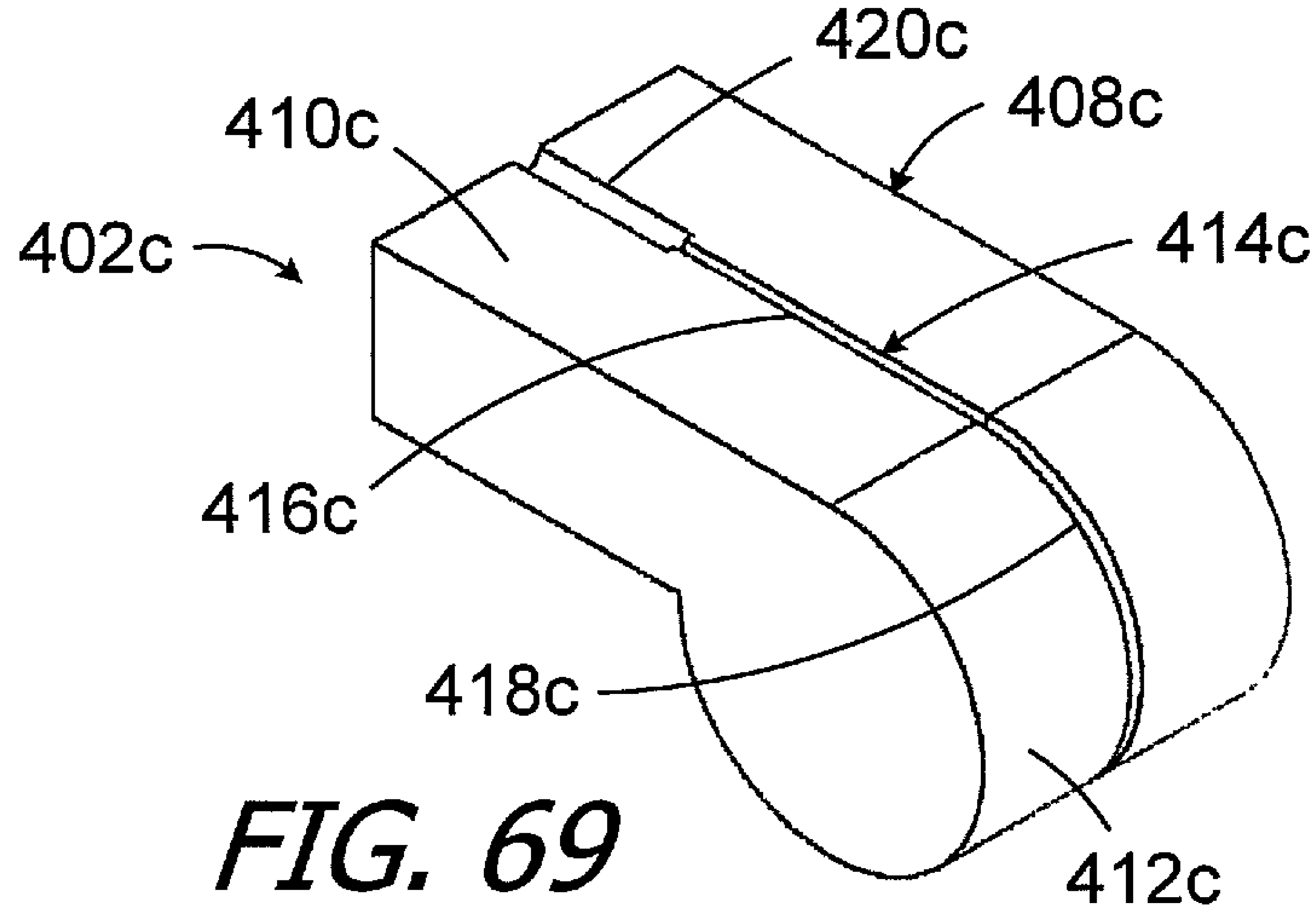

FIG. 69

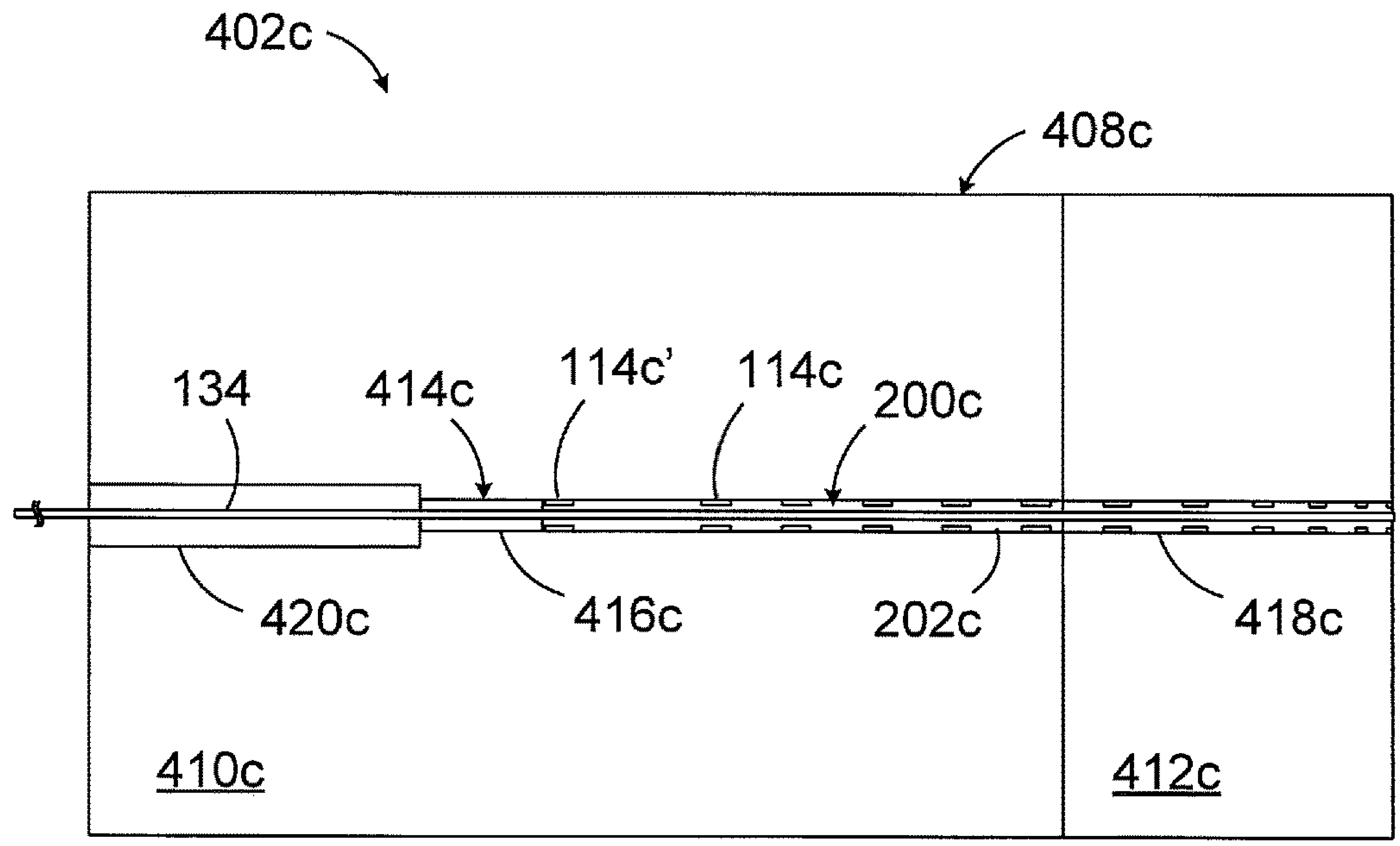

FIG. 70

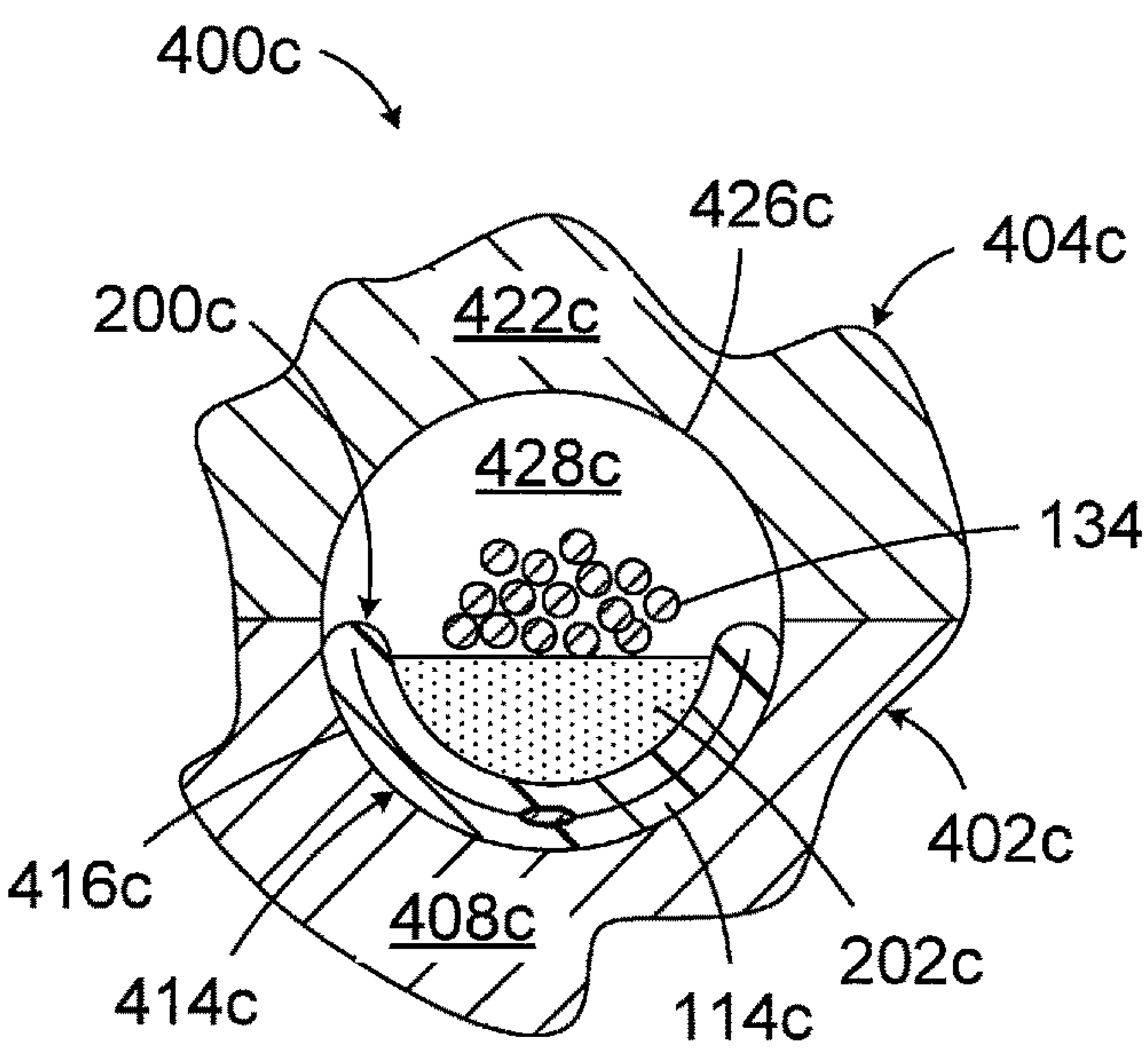

FIG. 71

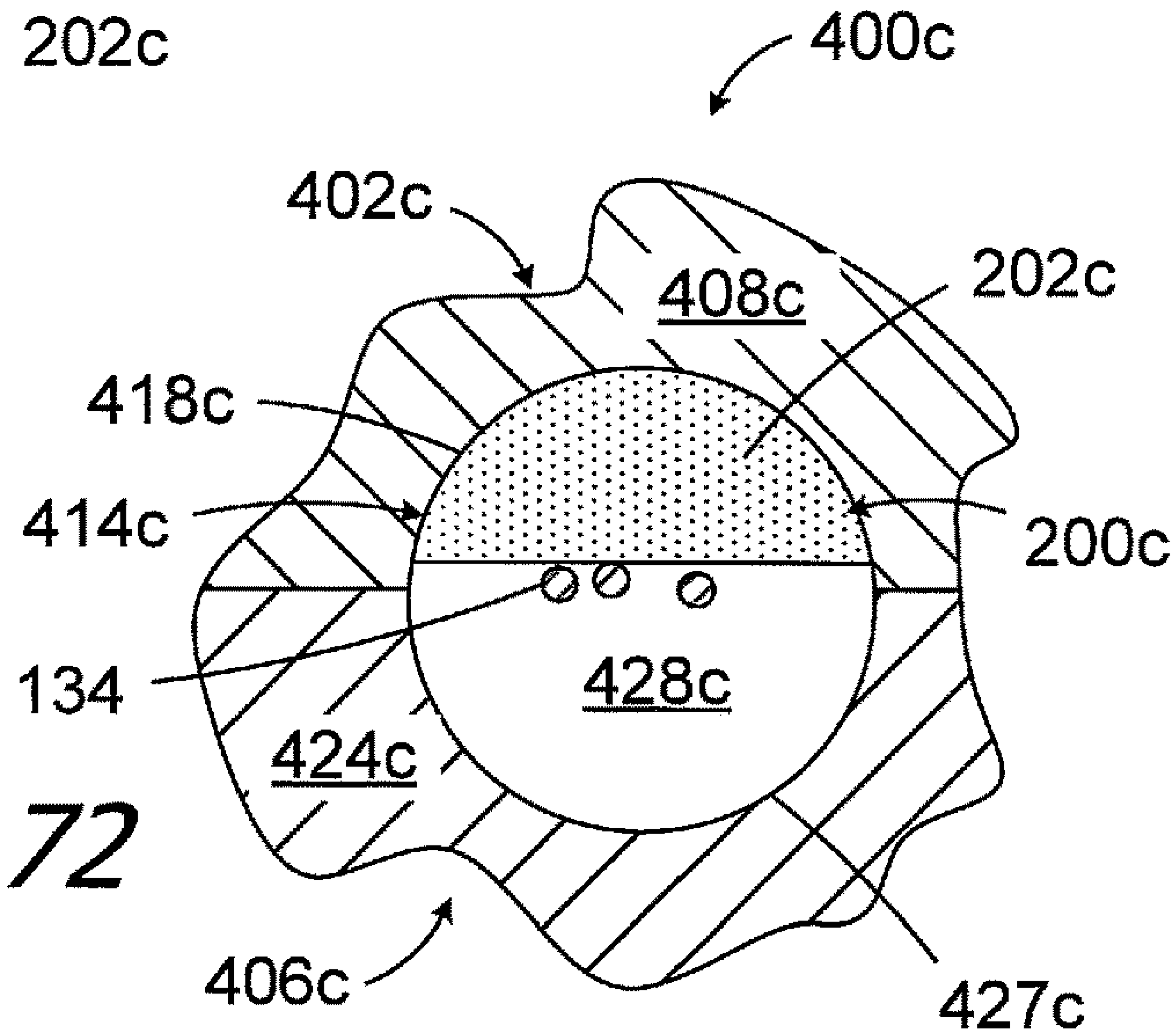

FIG. 72

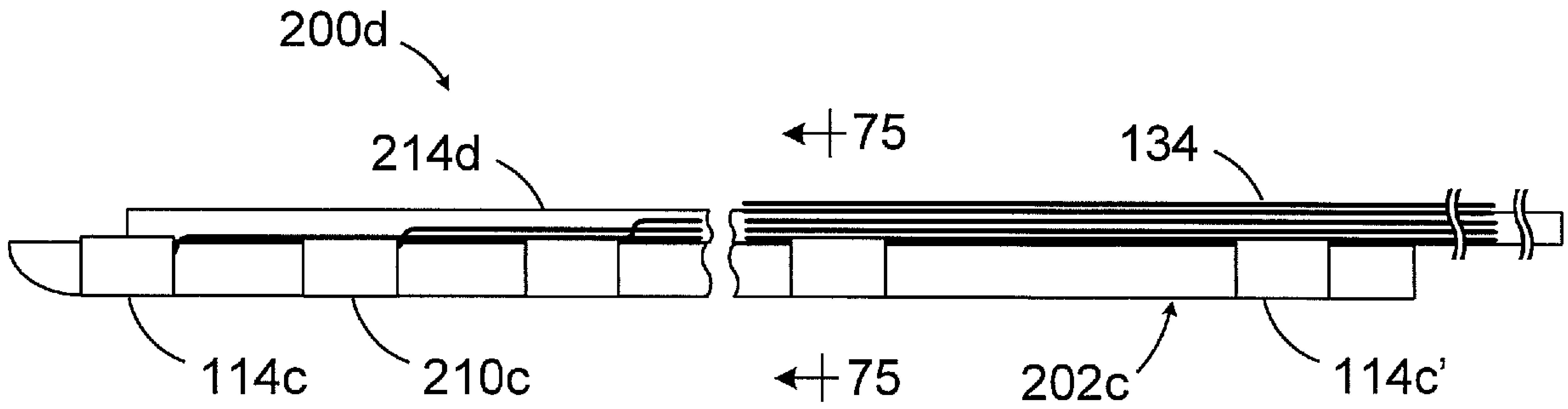

FIG. 73

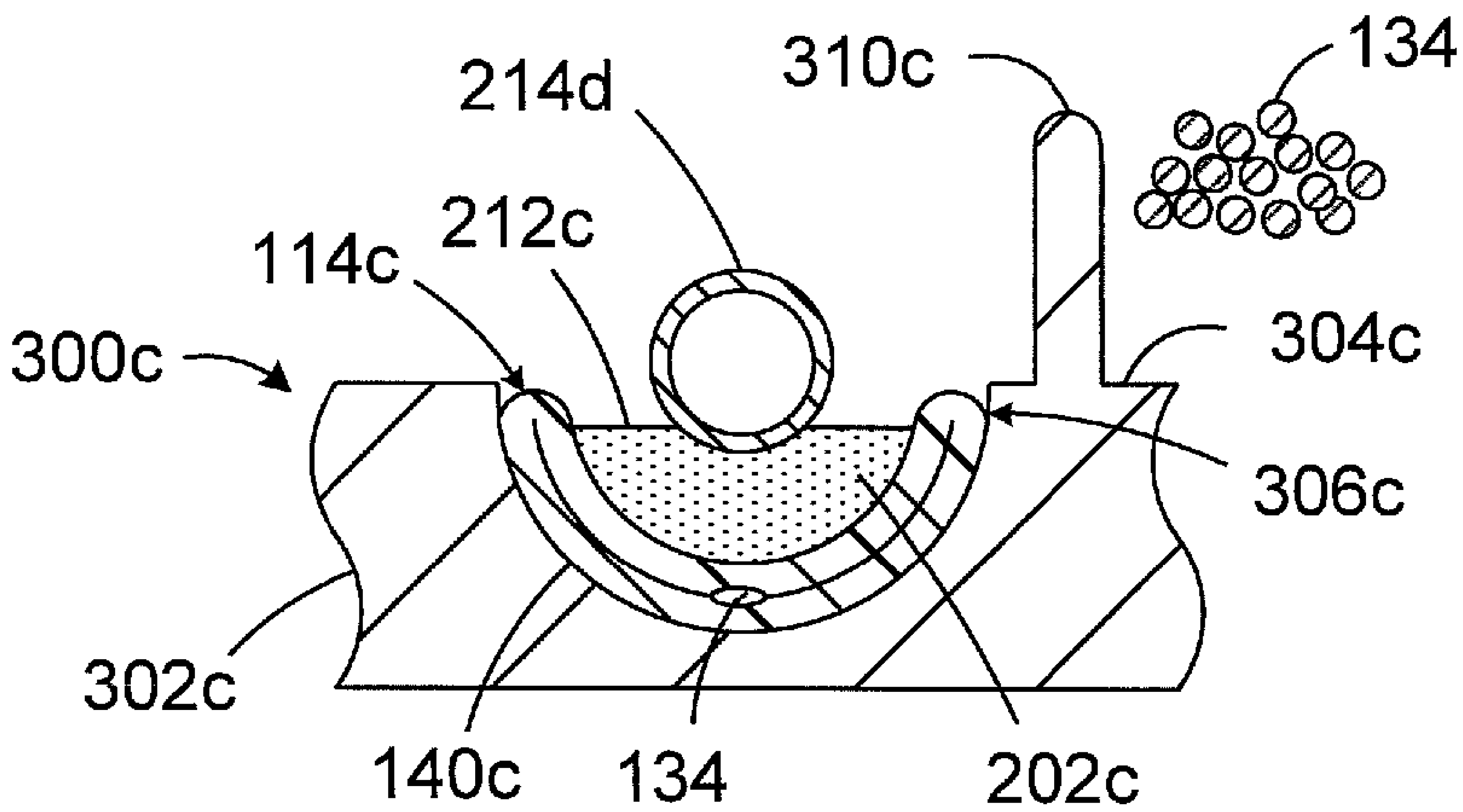

FIG. 74

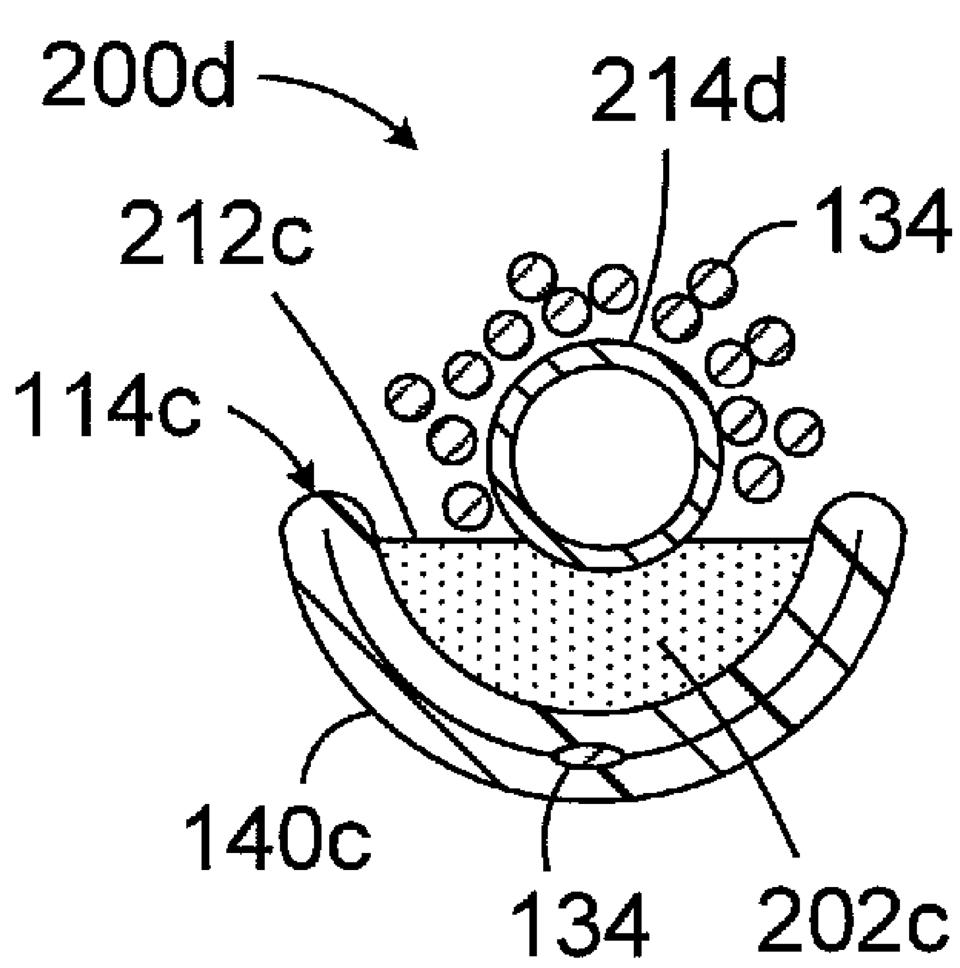

FIG. 75

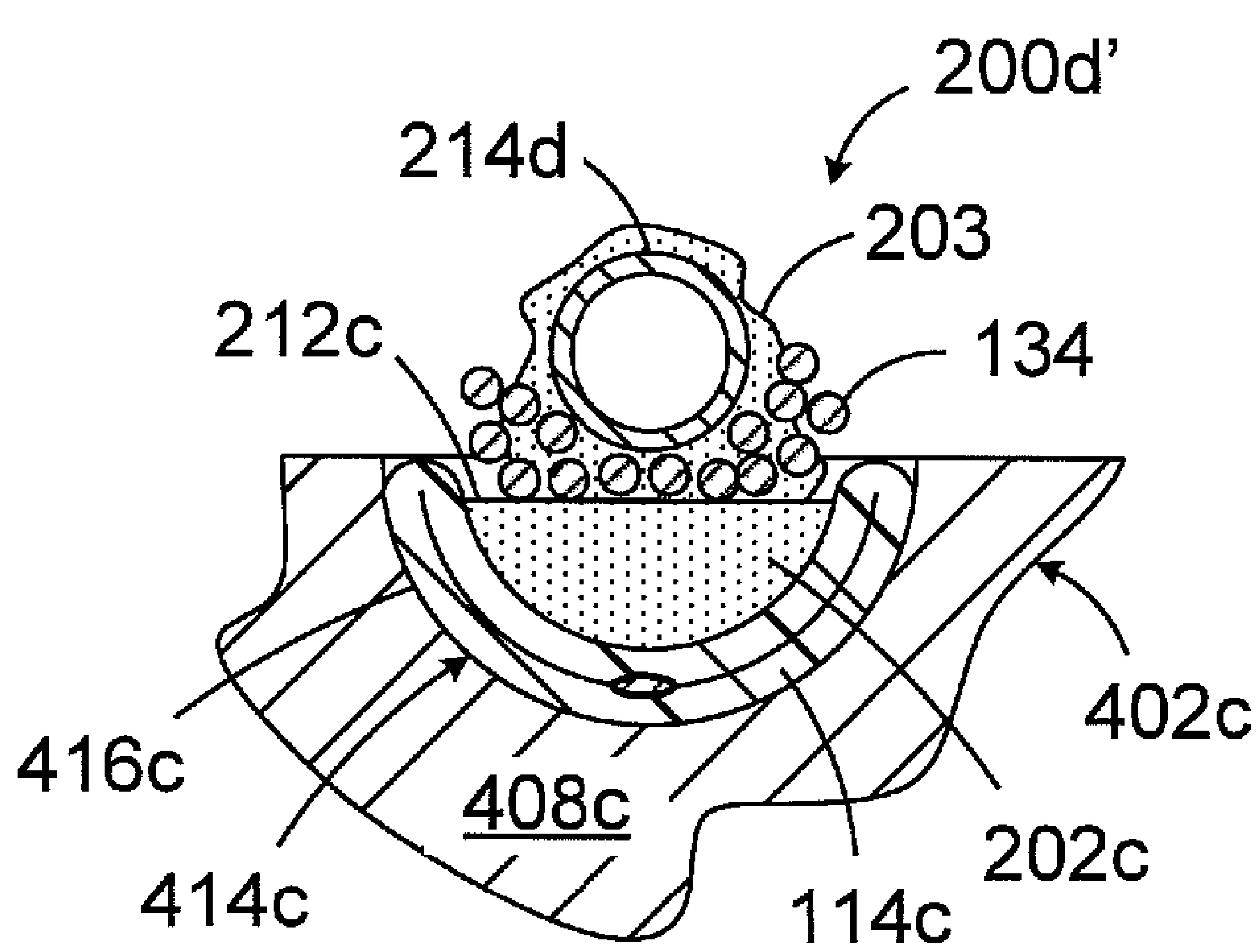

FIG. 75A

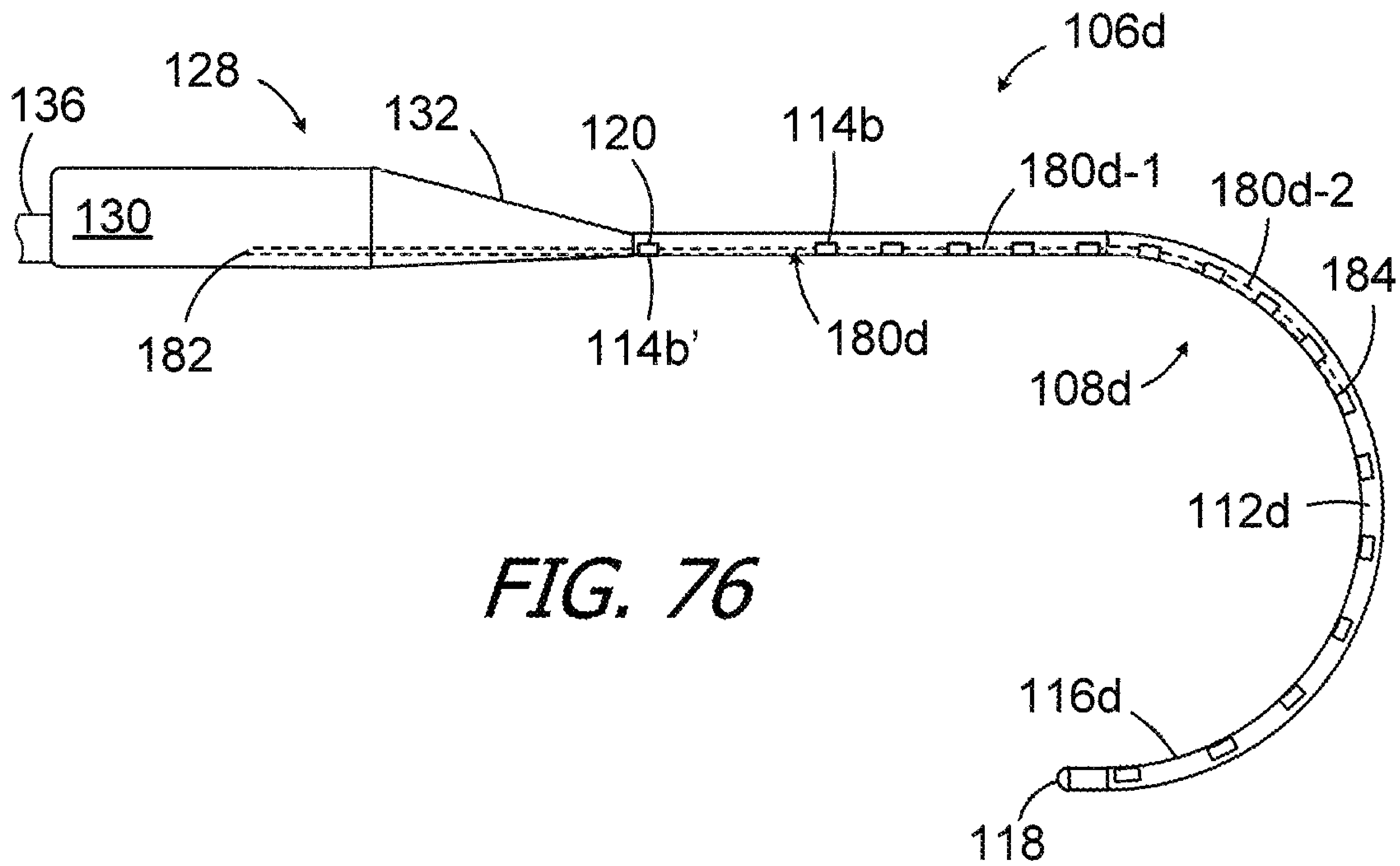
106d
128
136
132
120
114b
180d-1
180d-2
130
184
182
114b'
180d
108d
112d
116d
118

FIG. 76

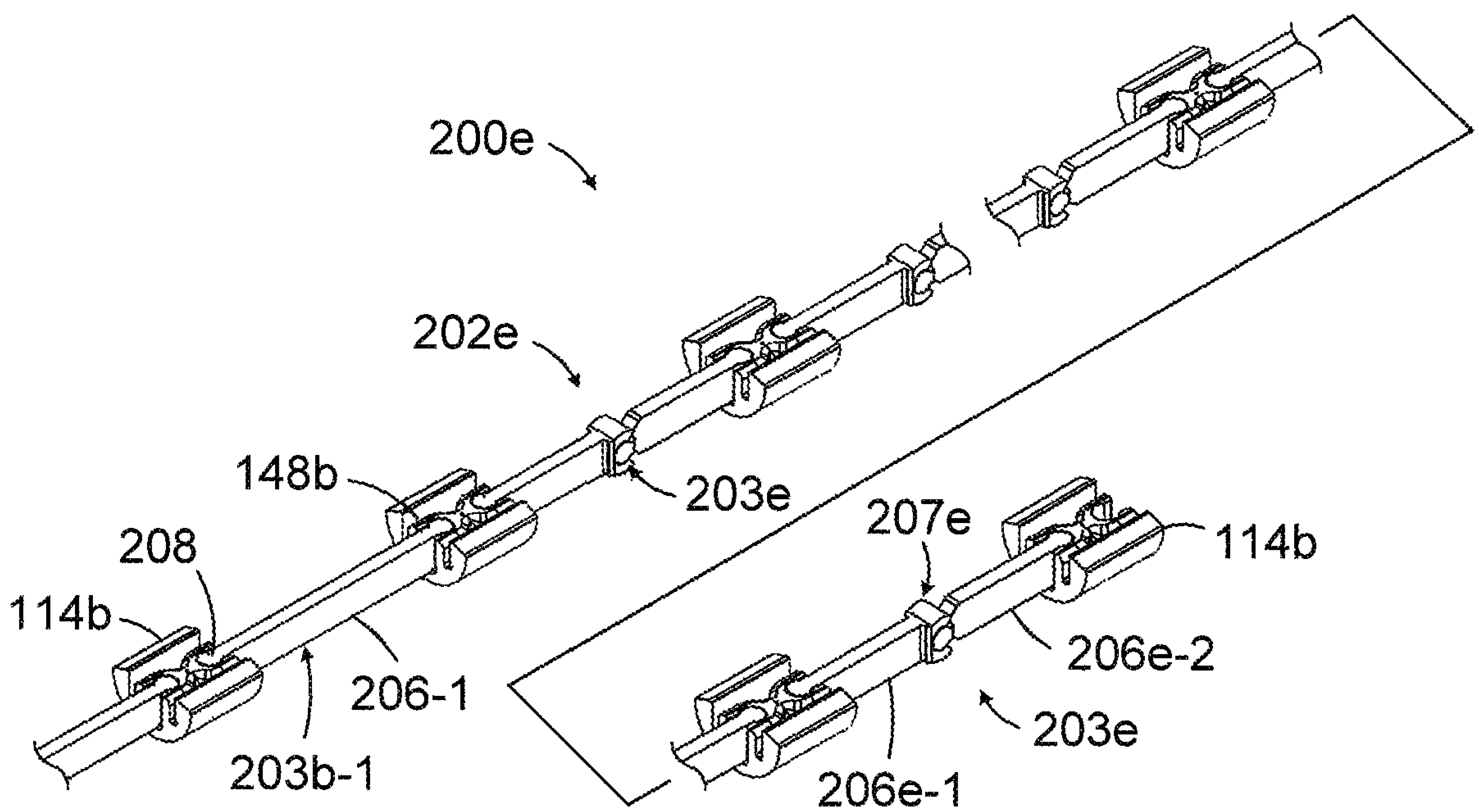
200e
202e
148b
203e
207e
208
114b
114b
206e-2
206-1
203e
203b-1
206e-1

FIG. 77

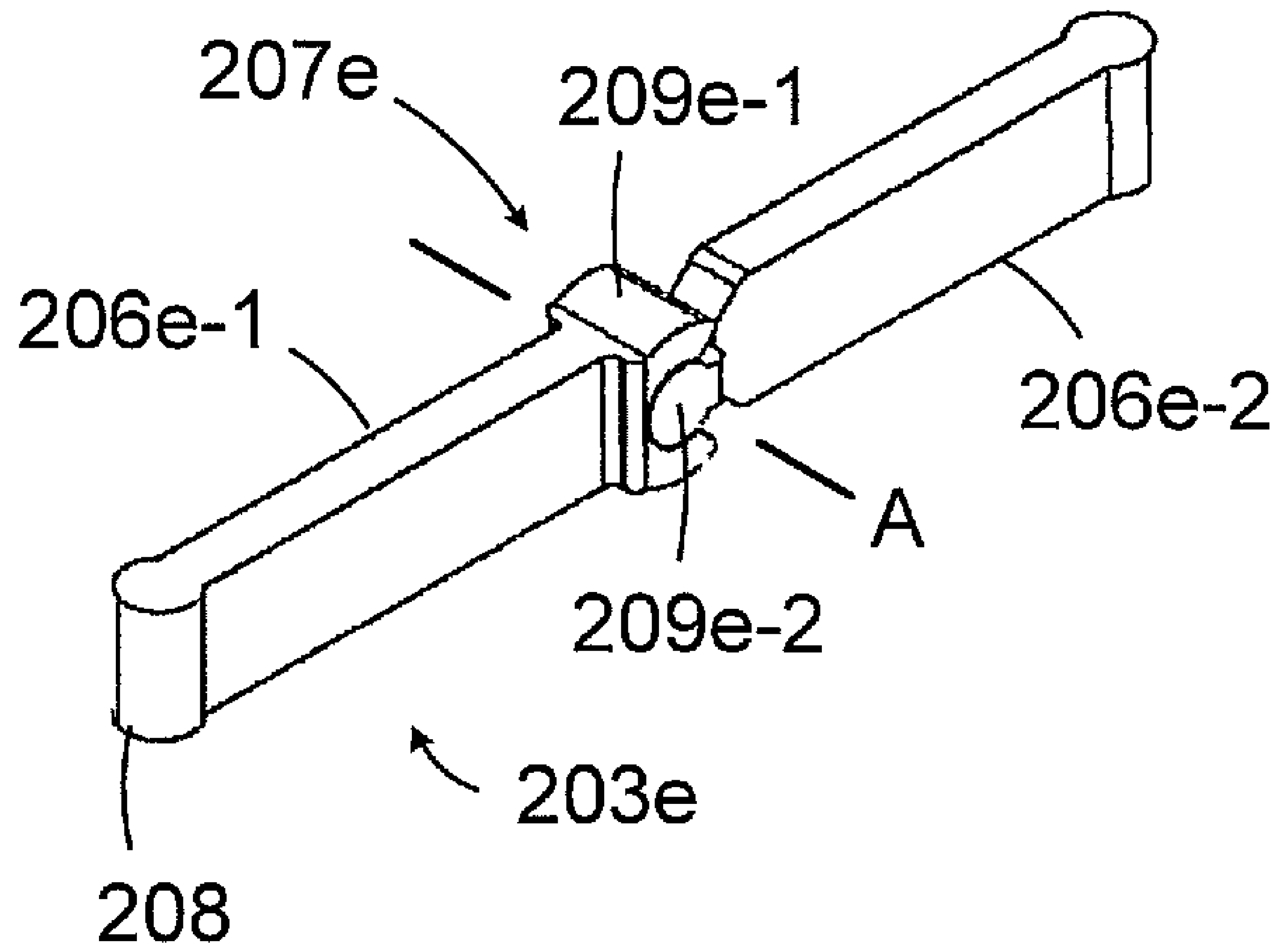

FIG. 78

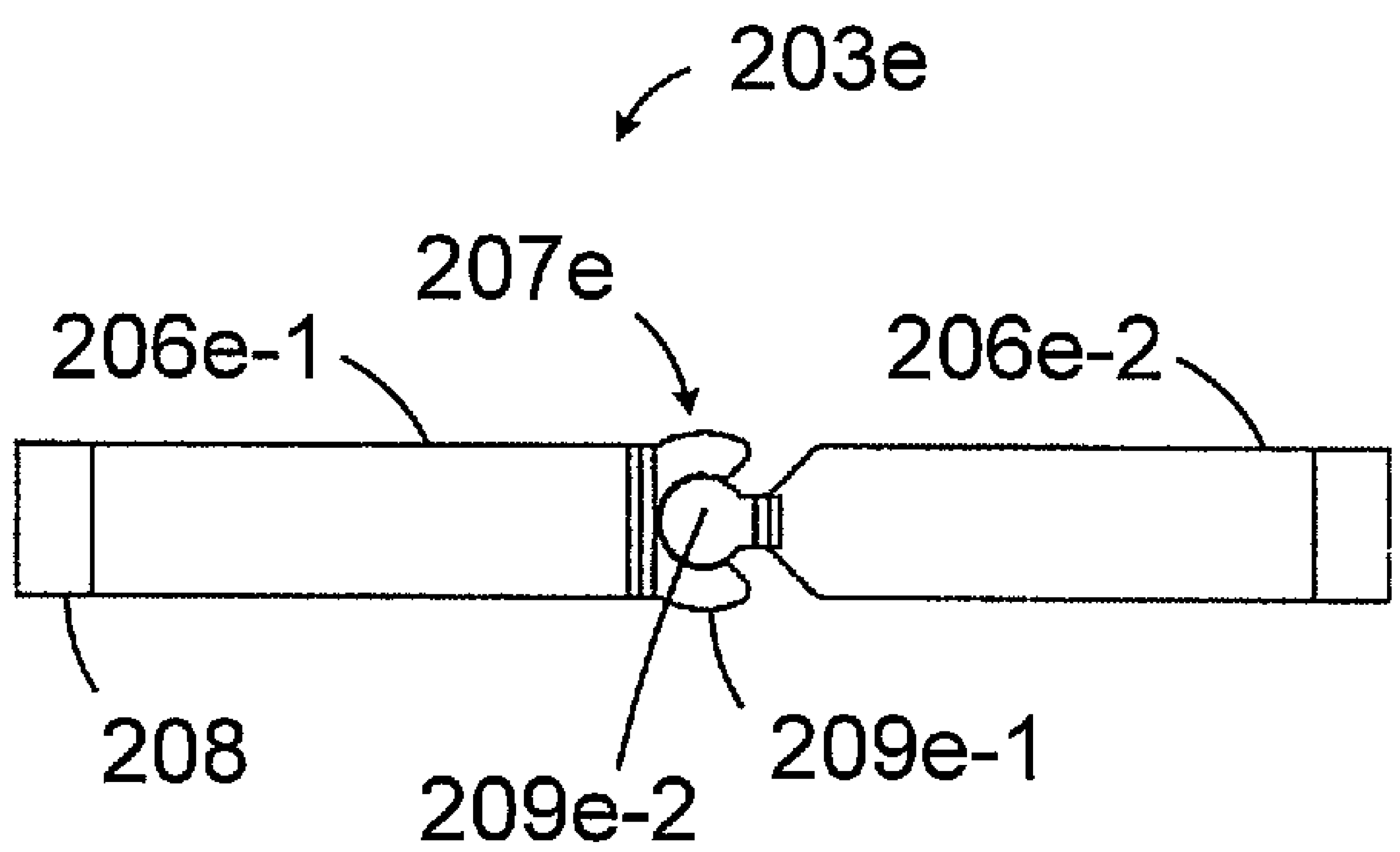

FIG. 79

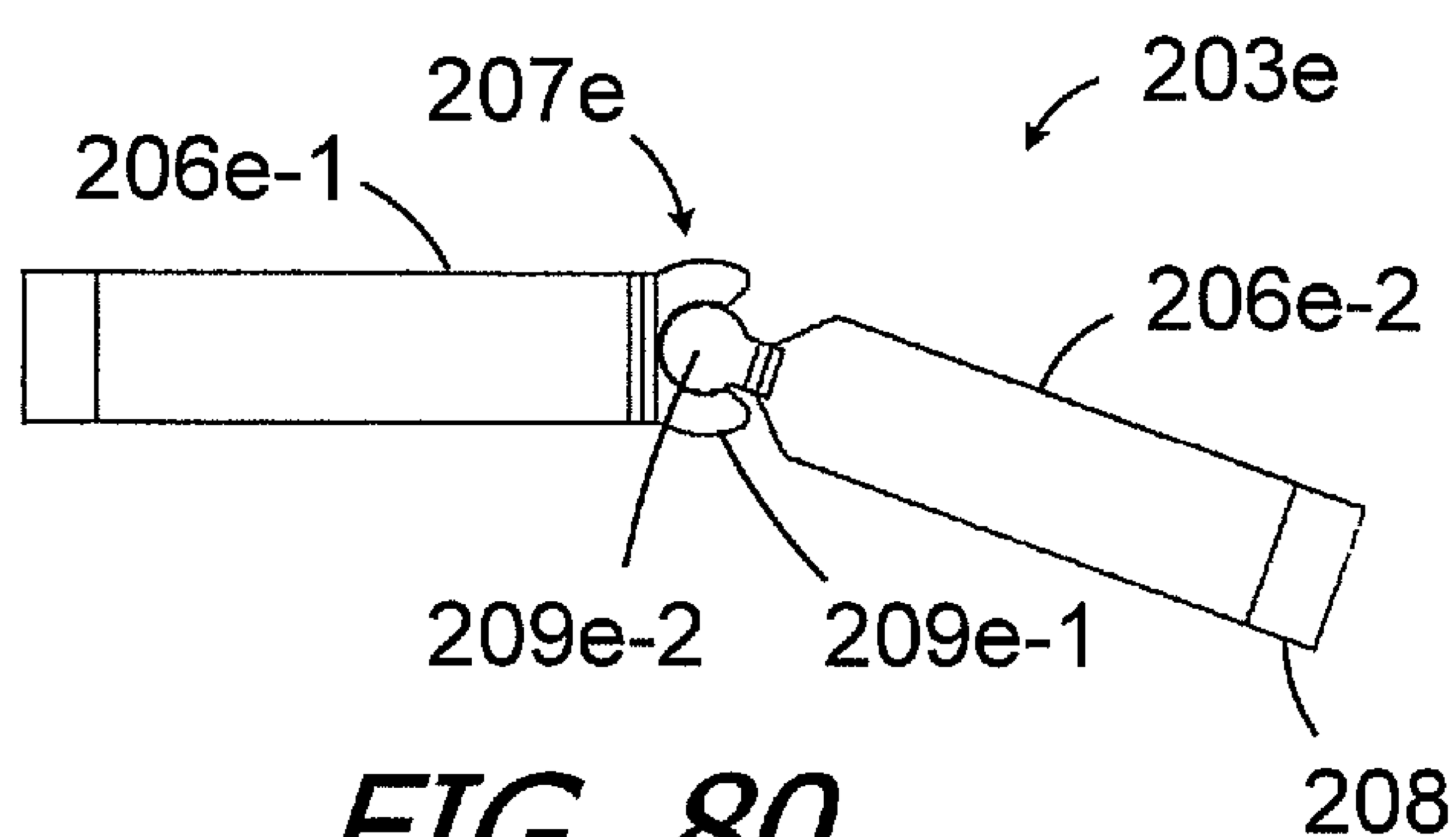

FIG. 80

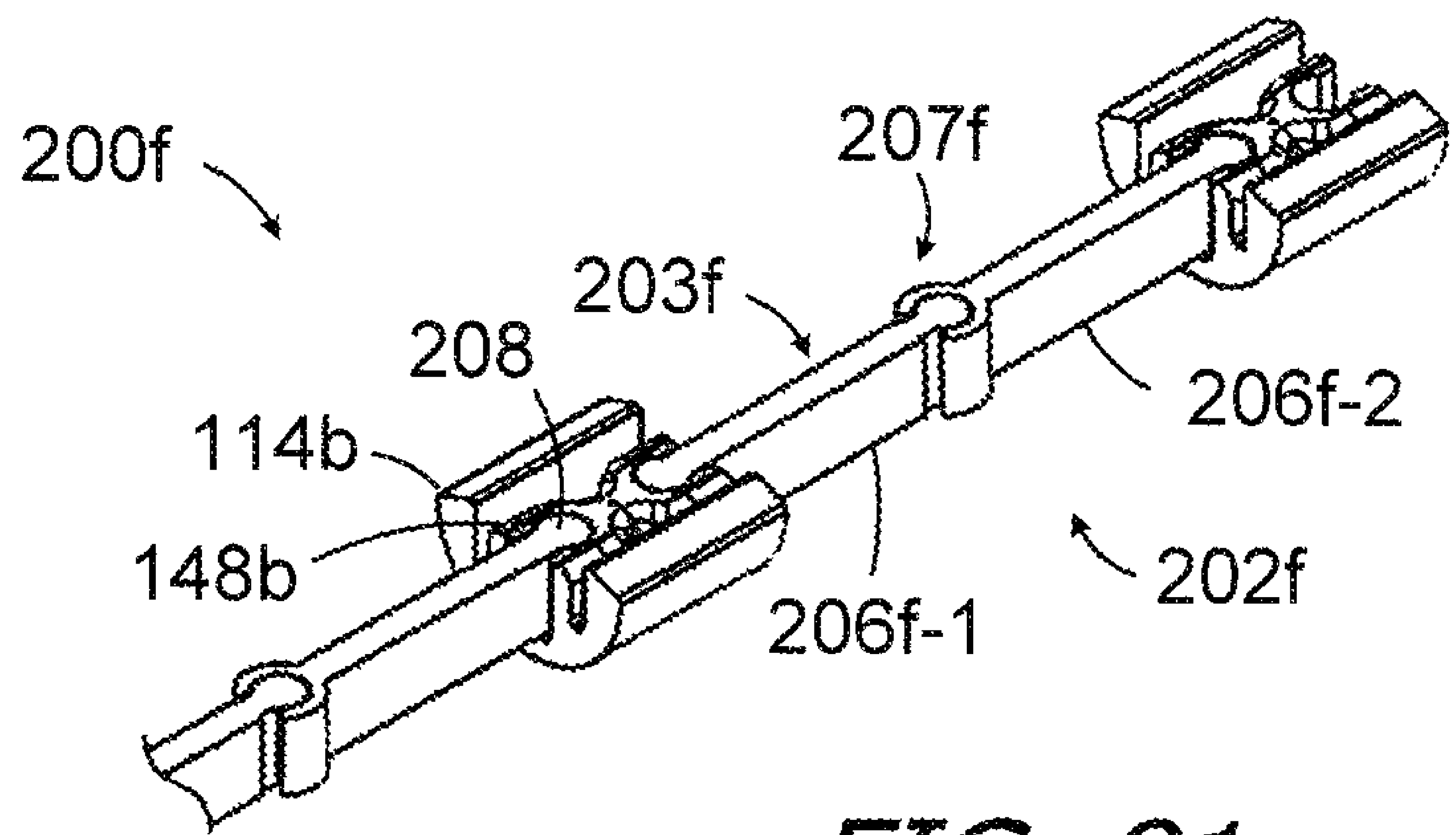

FIG. 81

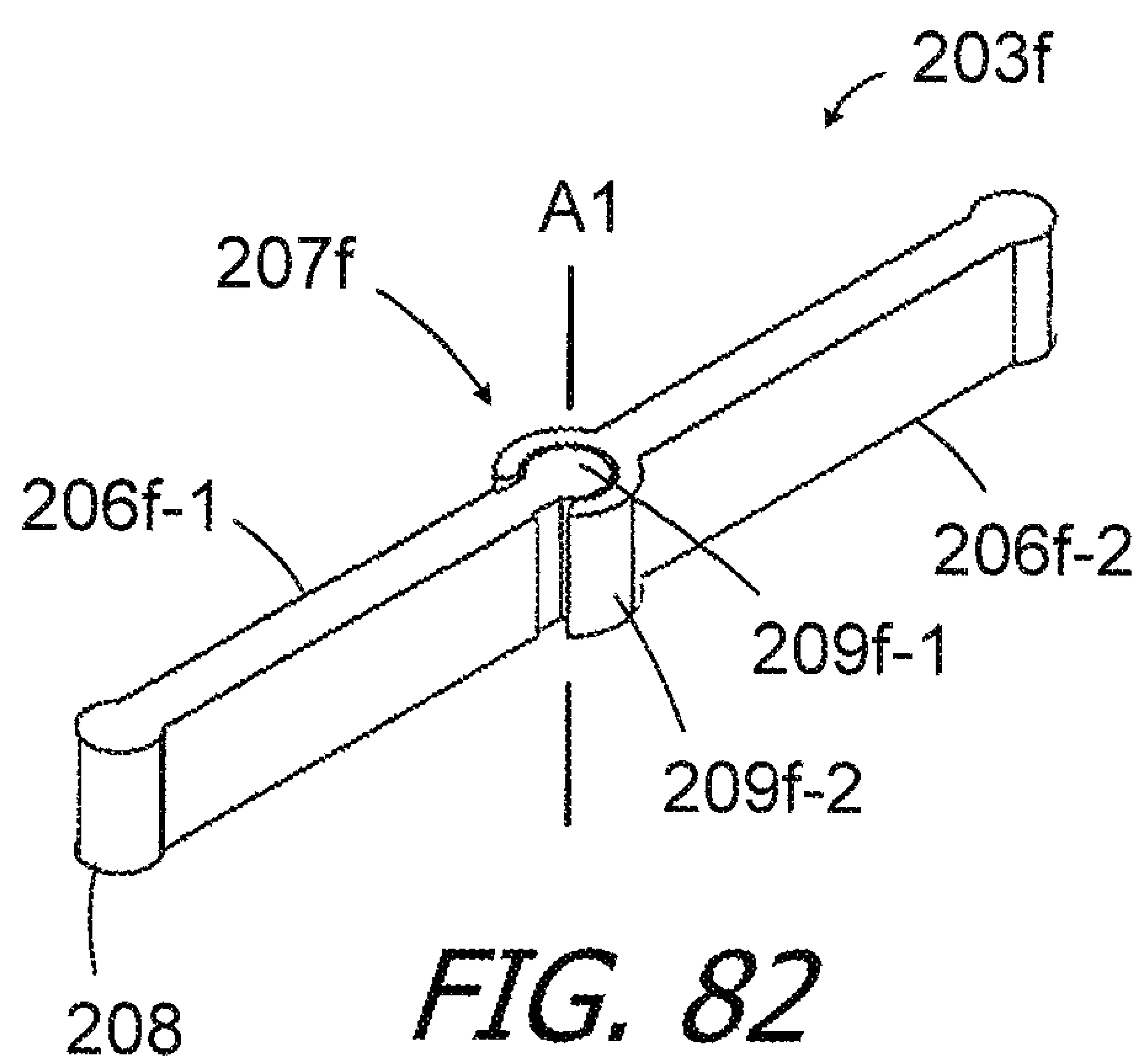

FIG. 82

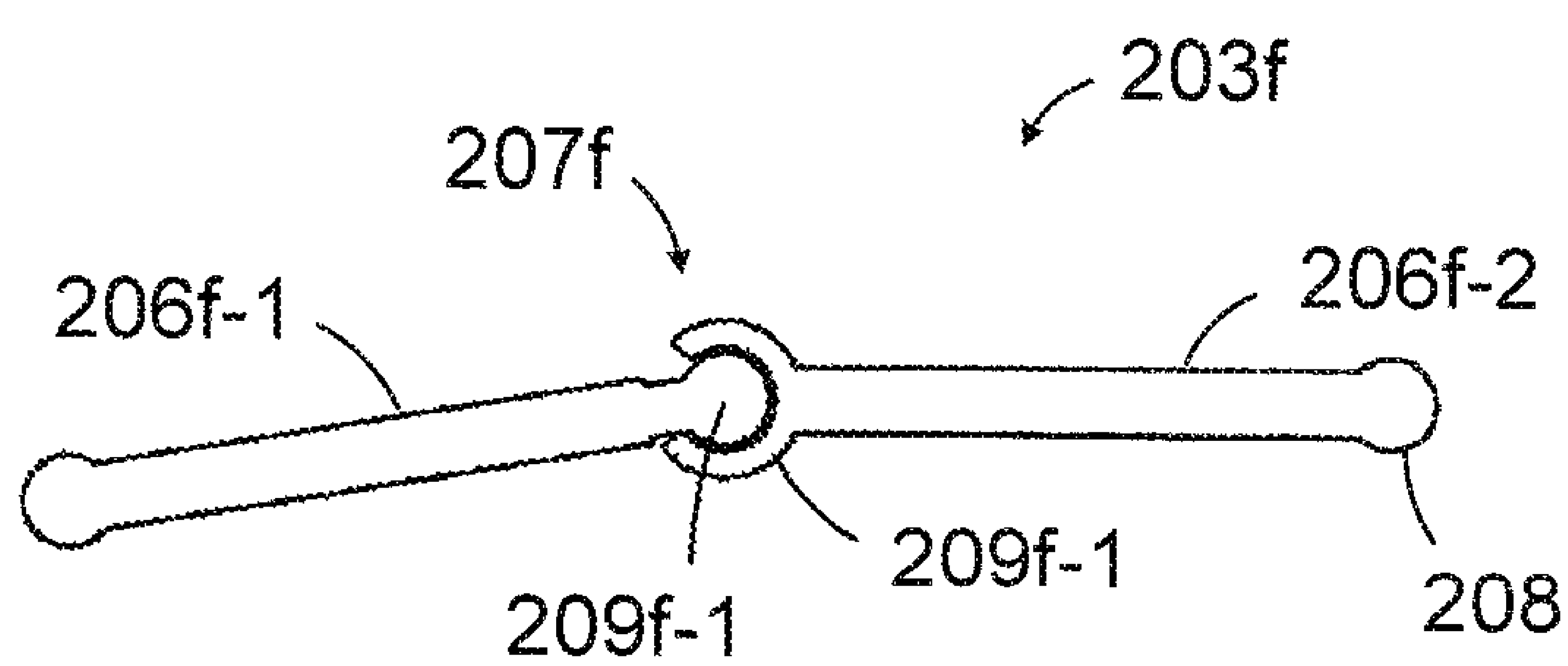

FIG. 83

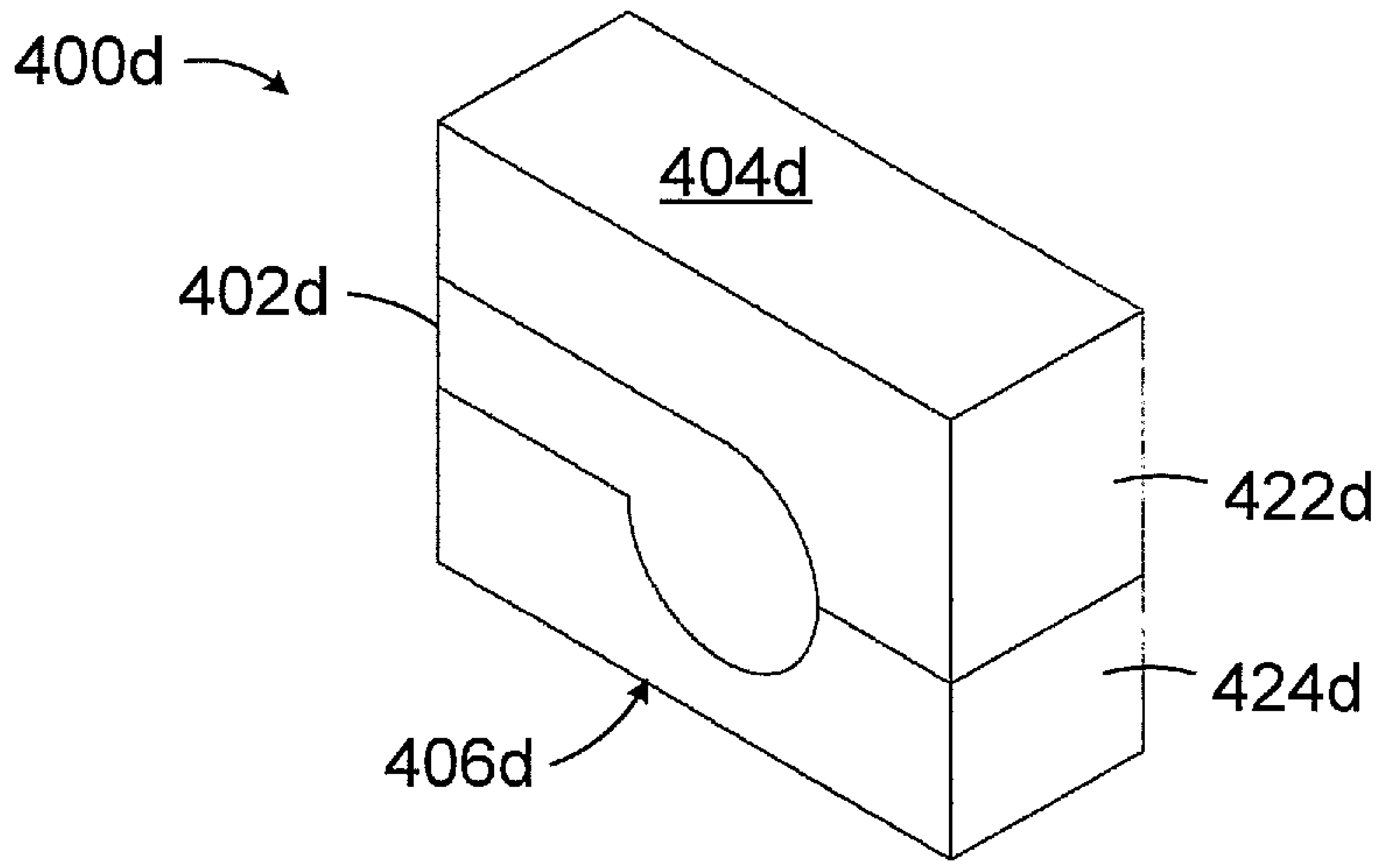
400d
404d
402d
422d
424d
406d

FIG. 84

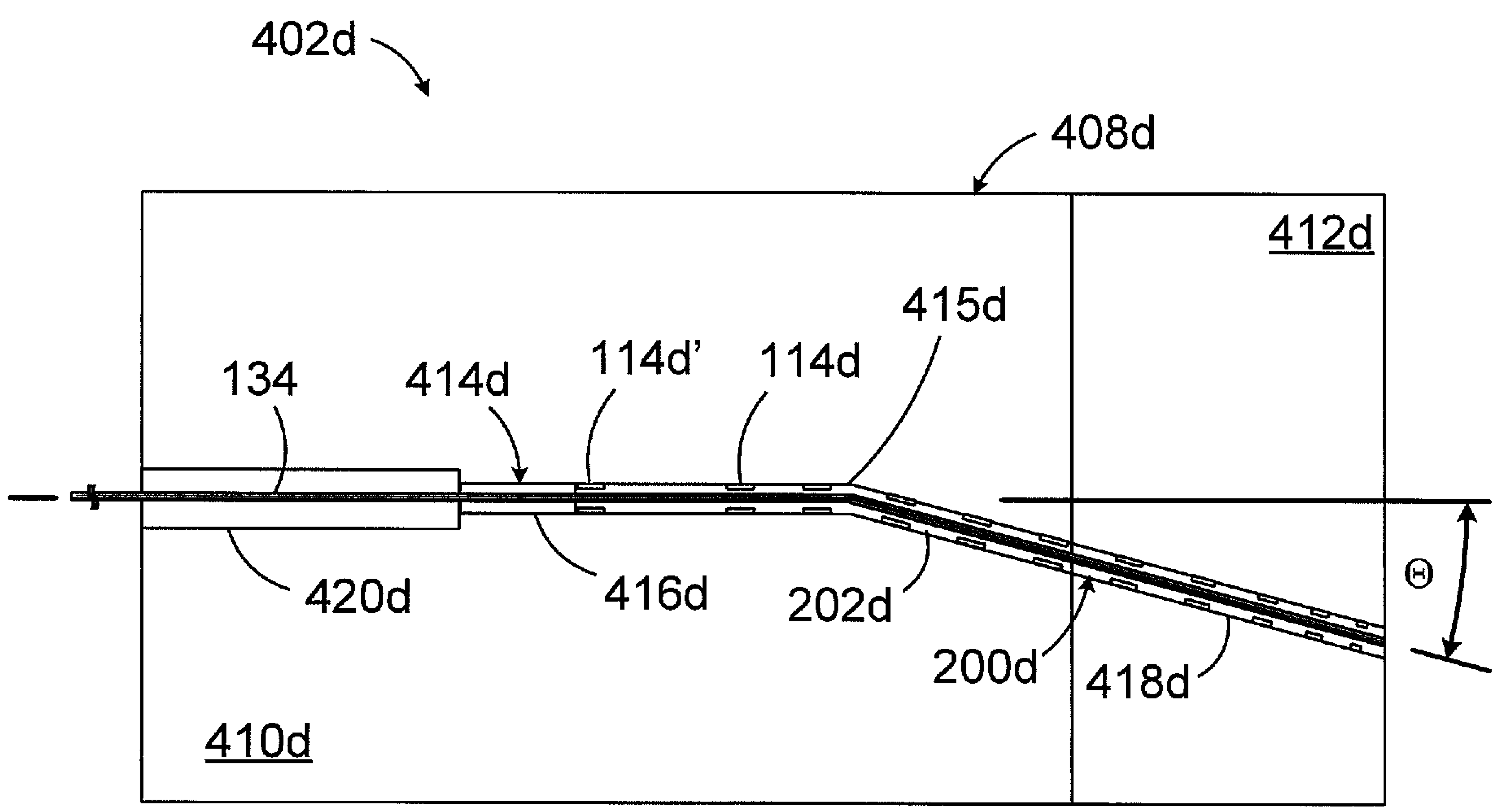
402d
408d
412d
415d
134
414d
114d'
114d
420d
416d
202d
Θ
200d
418d
410d

FIG. 85

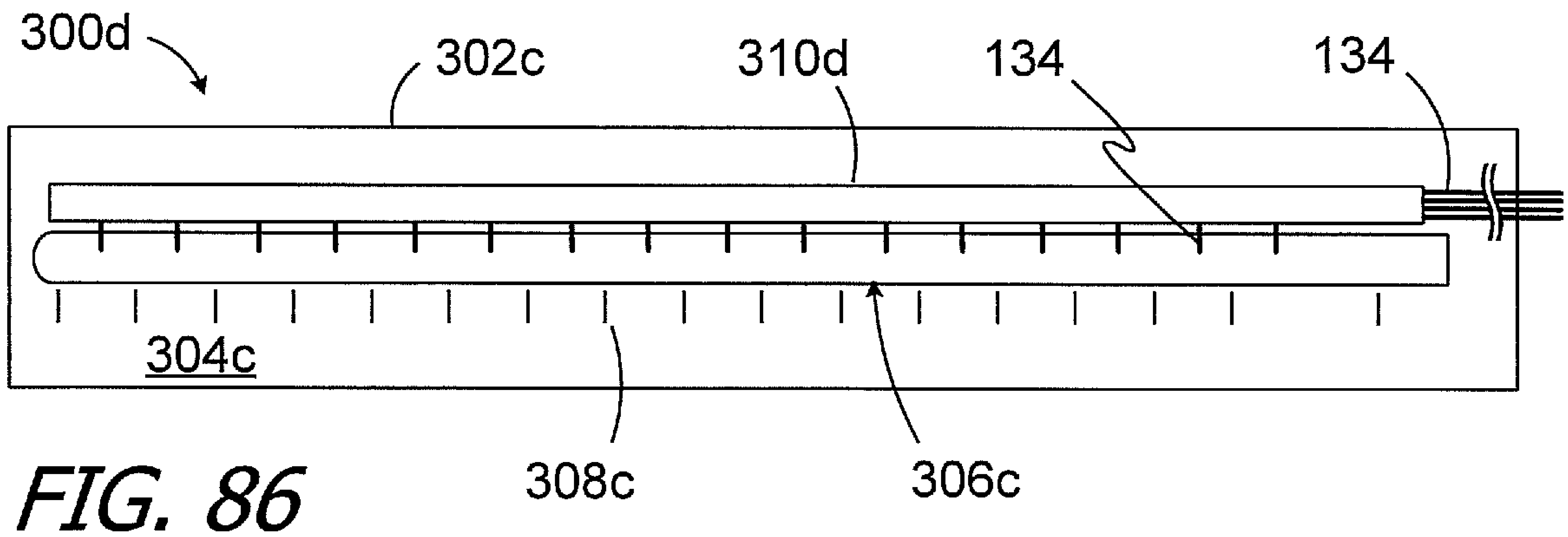

FIG. 86

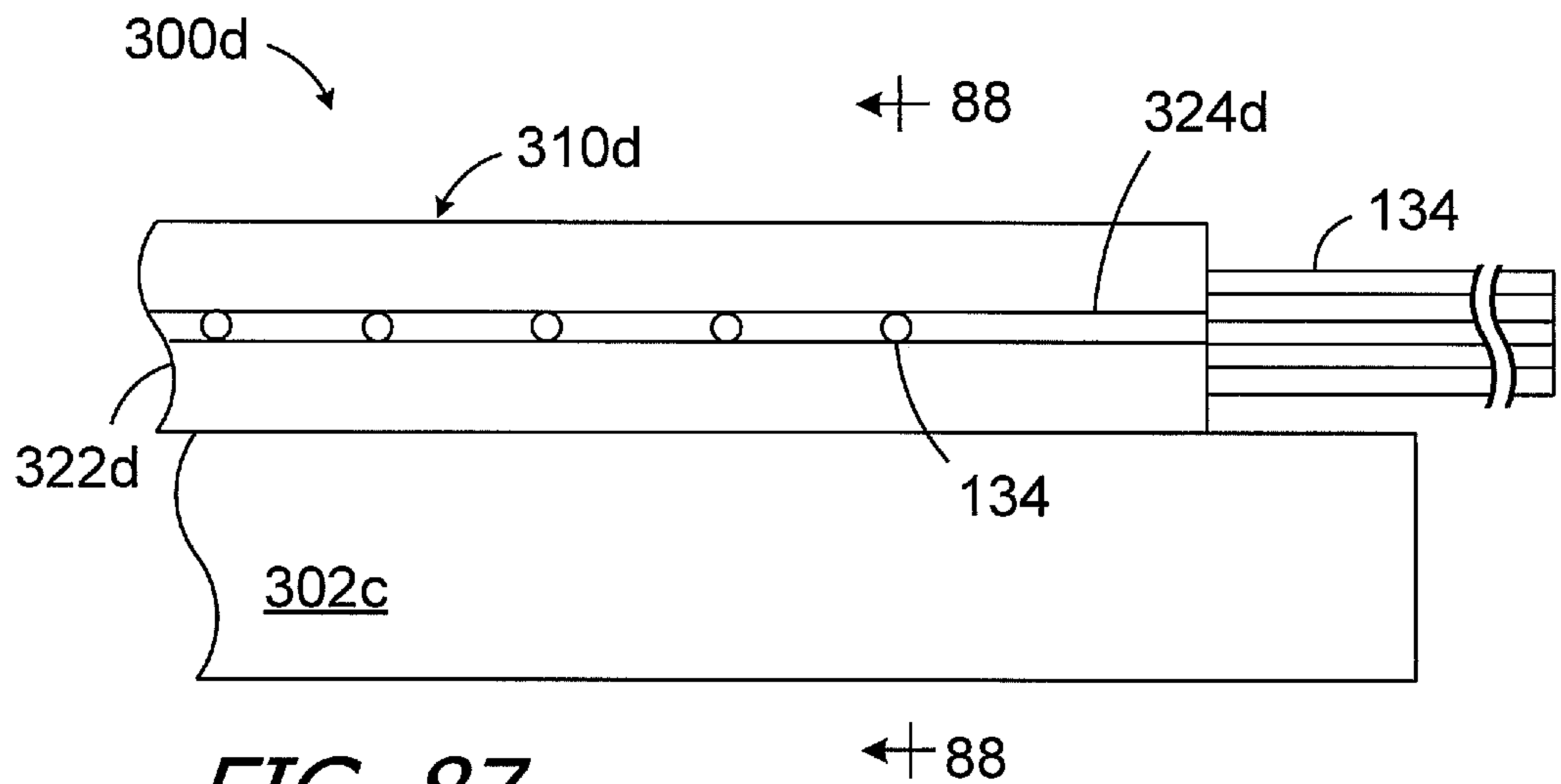

FIG. 87

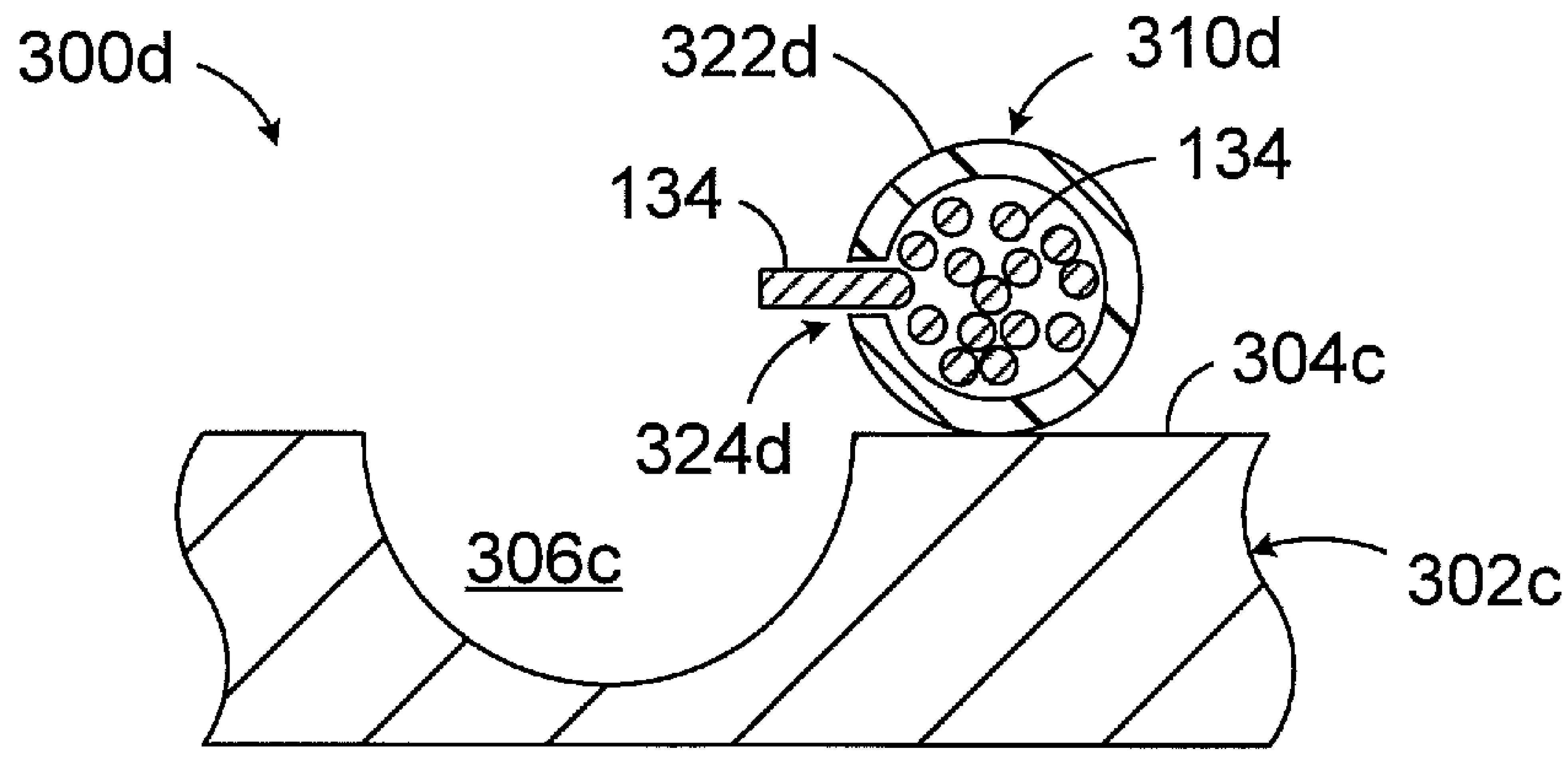

FIG. 88

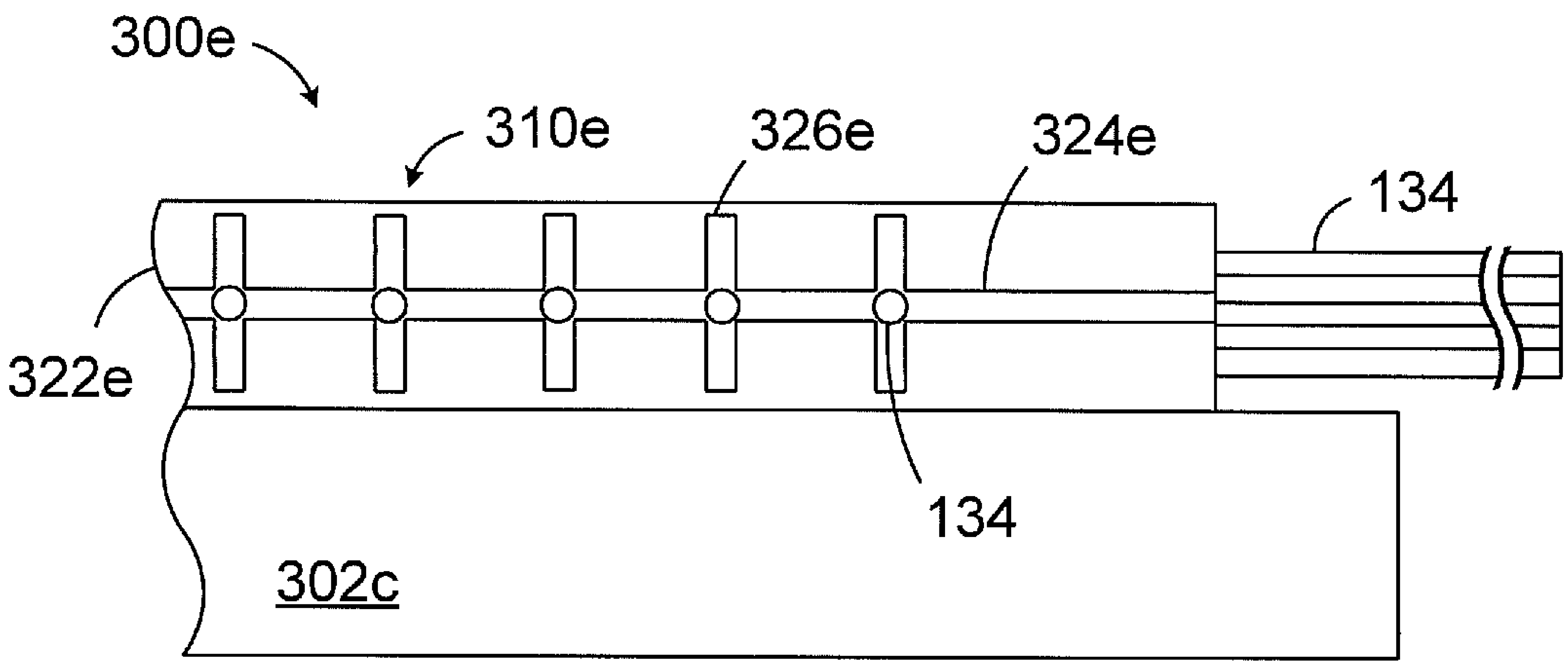
300e
310e
326e
324e
134
322e
134
302c

FIG. 89

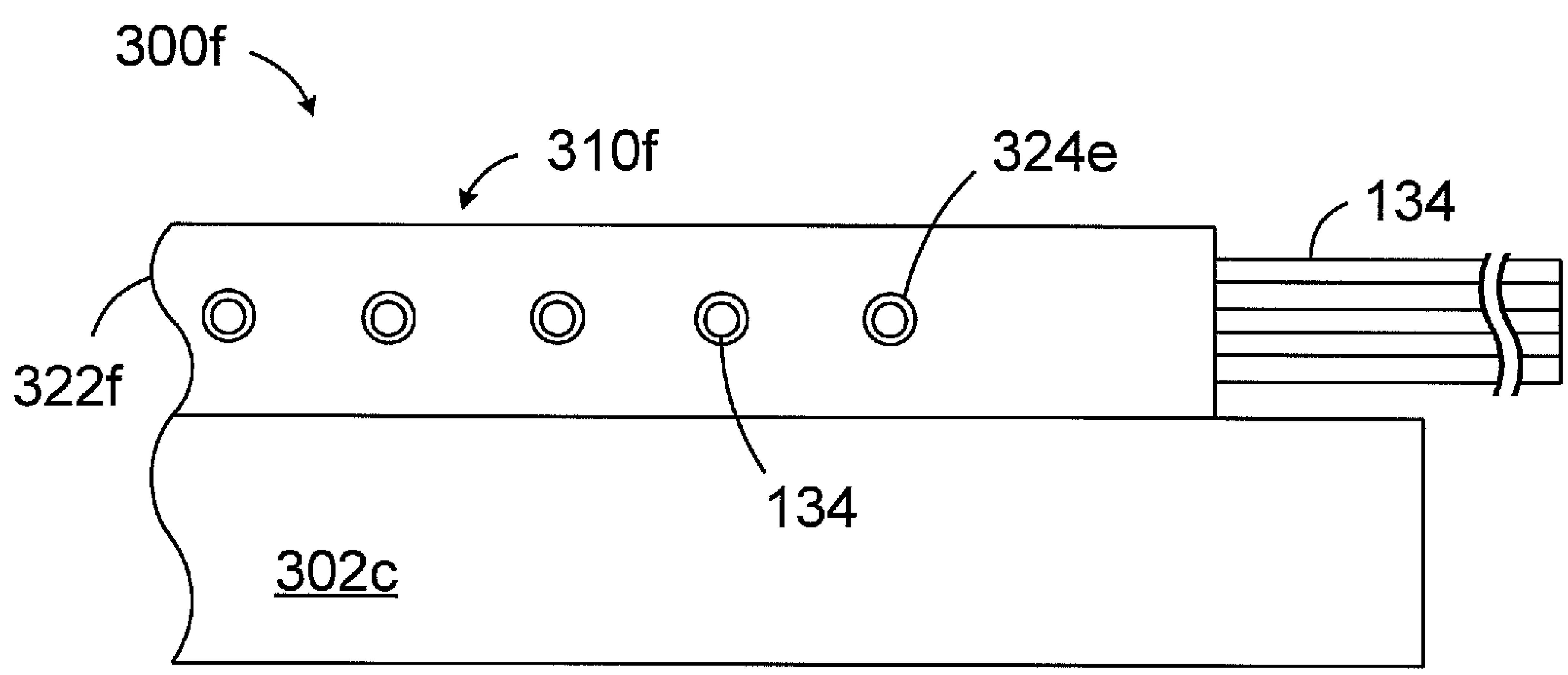
300f
310f
324e
134
322f
134
302c

FIG. 90

COCHLEAR IMPLANTS INCLUDING ELECTRODE ARRAYS AND METHODS OF MAKING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is the U.S. National Stage of PCT App. Ser. No. PCT/US2017/064231, filed Dec. 1, 2017, which claims priority to U.S. Prov. App. Ser. No. 62/428,668, filed Dec. 1, 2016.

BACKGROUND

1. Field

The present disclosure relates generally to the implantable portion of implantable cochlear stimulation (or "ICS") systems and, in particular, to electrode arrays.

2. Description of the Related Art

ICS systems are used to help the profoundly deaf perceive a sensation of sound by directly exciting the intact auditory nerve with controlled impulses of electrical current. Ambient sound pressure waves are picked up by an externally worn microphone and converted to electrical signals. The electrical signals, in turn, are processed by a sound processor, converted to a pulse sequence having varying pulse widths, rates, and/or amplitudes, and transmitted to an implanted receiver circuit of the ICS system. The implanted receiver circuit is connected to an implantable lead with an electrode array that is inserted into the cochlea of the inner ear, and electrical stimulation current is applied to varying electrode combinations to create a perception of sound. The electrode array may, alternatively, be directly inserted into the cochlear nerve without residing in the cochlea. A representative ICS system is disclosed in U.S. Pat. No. 5,824,022, which is entitled "Cochlear Stimulation System Employing Behind-The-Ear Sound processor With Remote Control" and incorporated herein by reference in its entirety. Examples of commercially available ICS sound processors include, but are not limited to, the Harmony™ BTE sound processor, the Naida™ CI Q Series sound processor and the Neptune™ body worn sound processor, which are available from Advanced Bionics.

As alluded to above, some ICS systems include an implantable cochlear stimulator (or "cochlear implant") having a lead with an electrode array, a sound processor unit (e.g., a body worn processor or behind-the-ear processor) that communicates with the cochlear implant, and a microphone that is part of, or is in communication with, the sound processor unit. The cochlear implant electrode array, which is formed by a molding process, includes a flexible body formed from a resilient material such as liquid silicone rubber ("LSR") and a plurality of electrically conductive contacts (e.g., sixteen platinum contacts) spaced along a surface of the flexible body. The contacts of the array are connected to lead wires that extend through the flexible body. Once implanted, the contacts face the modiolus within the cochlea.

The present inventors have determined that conventional methods of manufacturing electrode arrays are susceptive to improvement. The electrically conductive contacts, which must have a clean exposed surface to function properly, are masked during the molding process to prevent the LSR or other resilient material from covering the contacts. In some conventional processes, the contacts are welded to an iron strip and the lead wires are welded to the contacts while they are supported on iron strip. The iron strip masks portions of the contacts. The contacts, iron strip and lead wires are then placed into a mold that is configured to accommodate the iron strip. Resilient material is injected into the mold to form the flexible body of the electrode array through an overmolding process. The electrode array is removed from the mold once the resilient material has cured. The iron strip is then etched away from the contacts, in a bath of nitric acid or hydrochloric acid, thereby exposing the contacts. The contacts must be cleaned after the acid bath. The acid bath and cleaning take approximately 8 hours. The present inventors have determined that it would be desirable to avoid the use of harsh chemicals and the production delay associated therewith. The present inventors have also determined that welded masks can result in an uneven and uncontrolled contact surface, with small granulations in surface structure, which is more likely to experience biofilm and fibrous tissue growth than a smooth surface. Irregular surfaces are also likely to result in electrical impedances that vary from contact to contact. Exemplary methods of manufacturing electrode arrays are disclosed in U.S. Pat. Pub. No. 2011/0016710.

The present inventors have also determined that conventional electrode arrays are susceptive to improvement. For example, conventional electrode arrays can buckle during the insertion process, which necessitates repositioning and can result in damage to any still functioning hair cells in the cochlea that allow residual hearing to occur. In particular, when a thin electrode array (e.g., diameter of about 0.33 mm) that is configured for placement against the lateral wall is inserted into an opening in the cochlea, such as an opening formed by the "round window" technique or a cochleostomy, the base portions of thin electrode arrays sometimes buckle mid-way through the insertion procedure. Exemplary methods of stiffening electrode arrays are disclosed in U.S. Pat. Nos. 8,249,724, 8,812,121, 8,880,193, 9,033,869, 9,037,267, and 9,492,654 and U.S. Pat. Pub. No. 2011/0137393.

The present inventors have determined that conventional methods of making electrode arrays are susceptive to improvement. For example, some conventional methods involve the use of electrode array assemblies that include a plurality of conductive contacts which are respectively connected to a plurality of lead wires. A carrier (or "bridge" formed from a silicone adhesive is then applied to the contacts and lead wires prior to the remainder of the electrode array being molded onto the assembly. One example of a method that involves the use of such a bridge is disclosed in U.S. Pat. Pub. No. 2011/0016710. The present inventors have determined that placing the electrode array subassembly in a curved mold to form the carrier over lead wires can cause the lead wires to break.

SUMMARY

A method of forming a cochlear implant electrode array in accordance with one of the present inventions includes the steps of positioning a contact array assembly, which includes at least one carrier and a plurality of electrically conductive contacts on the at least one carrier, in a mold, removing at least a portion of the at least one carrier from the mold without removing the plurality of electrically conductive contacts from the mold, and introducing resilient material into the mold after the at least one carrier has been removed to form a flexible body.

A contact array assembly for use in during the manufacture of a cochlear implant electrode array in accordance with one of the present inventions includes at least one carrier and a plurality of electrically conductive contacts, which are sized and shaped for insertion into the cochlea, removably mounted on the at least one carrier.

A cochlear implant in accordance with one of the present inventions includes a housing, an antenna within the housing, a stimulation processor, and an electrode array operably connected to the stimulation processor. The electrode array may include a flexible body and a plurality of electrically conductive contacts, with a tissue contact surface and at least one cylindrical aperture, carried on the flexible body such that the tissue contact surfaces are exposed and portions of the flexible body extend through the at least one cylindrical aperture of at least some of the electrically conductive contacts.

A cochlear implant in accordance with one of the present inventions includes a housing, an antenna within the housing, a stimulation processor, and an electrode array operably connected to the stimulation processor. The electrode array may include a flexible body, a plurality of electrically conductive contacts, with a tissue contact surface and a pair of contact connectors, carried on the flexible body such that the tissue contact surfaces are exposed, and at least one relatively stiff, electrically non-conductive link with a pair of link connectors that connects two adjacent contacts to one another. The contact connectors and the link connectors may be respectively configured such that the link connectors can engage with, and disengage from, the contact connectors prior to formation of the flexible body.

A method of forming a cochlear implant electrode array including a flexible body, a plurality of electrically conductive contacts on the flexible body and a plurality of lead wires respectively connected to the plurality of electrically conductive contacts in accordance with one of the present inventions includes the steps of forming a contact array assembly by positioning the electrically conductive contacts and lead wires within a cavity in such a manner that one end of each lead wire is connected to a respective electrically conductive contact and the remainder of each lead wire is located outside of the cavity, and forming a carrier that defines a portion of the flexible body by introducing resilient material into the cavity while the remainder of each lead wire is located outside of the cavity, positioning the contact array assembly in a curved mold with the remainders of the lead wires located outside of the carrier and free to move relative to the carrier, and introducing resilient material into the curved mold to complete the flexible body.

There are a number of advantages associated with such methods and apparatus. For example, removing some or all of the carrier prior to molding eliminates the need for the post-molding etching processes associated with some conventional methods. Also, because the carrier is not associated with (and not in contact with) the tissue contact surfaces of the contacts, the present method and apparatus produce a smooth, clean surface that is less likely to experience biofilm and fibrous tissue grown after implantation or electrical impedances that vary from contact to contact. Keeping the lead wires out of the cavity in which the carrier is formed prevents the carrier from being formed over the lead wires. As a result, the lead wires will be free to move relative the remainder of the electrode array assembly when the electrode array assembly is placed in a curved mold, thereby reducing the likelihood that the lead wires will break.

The above described and many other features of the present inventions will become apparent as the inventions become better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Detailed descriptions of the exemplary embodiments will be made with reference to the accompanying drawings.

FIG. **1** is a plan view of a cochlear implant in accordance with one embodiment of a present invention.

FIG. **2** is a perspective view of a portion of the cochlear lead illustrated in FIG. **1**.

FIG. **3** is a perspective view of a portion of the cochlear lead illustrated in FIG. **1**.

FIG. **4** is a section view taken along line **4-4** in FIG. **2**.

FIG. **5** is a section view taken along line **5-5** in FIG. **2**.

FIG. **6** is a section view taken along line **6-6** in FIG. **2**.

FIG. **7** is a section view taken along line **7-7** in FIG. **2**.

FIG. **8** is a perspective view of a contact array assembly in accordance with one embodiment of the present invention.

FIG. **9** is another perspective view of the contact array assembly illustrated in FIG. **8**.

FIG. **10** is a perspective view of a portion of the contact array assembly illustrated in FIG. **8**.

FIG. **11** is a perspective view of one of the contacts in the contact array assembly illustrated in FIG. **8**.

FIG. **12** is an end view of the contact illustrated in FIG. **11**.

FIG. **13** is a perspective view of a portion of the contact array assembly illustrated in FIG. **8**.

FIG. **14** is a perspective view of one of the contacts in the contact array assembly illustrated in FIG. **8**.

FIG. **15** is an end view of the contact illustrated in FIG. **14**.

FIG. **16** is a perspective view of a portion of the contact array assembly illustrated in FIG. **8**.

FIG. **17** is a perspective view of one of the contacts in the contact array assembly illustrated in FIG. **8**.

FIG. **18** is an end view of the contact illustrated in FIG. **17**.

FIG. **19** is a plan view of the contact array assembly illustrated in FIG. **8** on a wire bonding fixture.

FIG. **20** is a section view taken along line **20-20** in FIG. **19**.

FIG. **21** is a plan view of the contact array assembly illustrated in FIG. **19** with wires bonded thereto.

FIG. **22** is a plan view of a mold in accordance with one embodiment of a present invention.

FIG. **23** is an exploded section view taken along line **23-23** in FIG. **22**.

FIG. **24** is a plan view of the contact array assembly illustrated in FIG. **8** on a portion of the mold illustrated in FIGS. **22** and **23** with wires bonded thereto.

FIG. **25** is a section view showing a portion of the contact array assembly illustrated in FIG. **8** on a portion of the mold illustrated in FIGS. **22** and **23** with wires bonded thereto.

FIG. **26** is a section view showing a portion of the contact array assembly illustrated in FIG. **8** on a portion of the mold illustrated in FIGS. **22** and **23** with wires bonded thereto.

FIG. **27** is a section view showing a portion of the contact array assembly illustrated in FIG. **8** in a mold with wires bonded thereto.

FIG. **28** is a side view of a portion of the cochlear lead in accordance with one embodiment of a present invention.

FIG. 29 is a plan view of a portion of a contact array assembly in accordance with one embodiment of the present invention.

FIG. 30 is a plan view of the contact array assembly illustrated in FIG. 29 on a portion of the mold illustrated in FIGS. 22 and 23 with wires bonded thereto.

FIG. 31 is a side view of a portion of cochlear lead in accordance with one embodiment of a present invention.

FIG. 32 is a perspective view of a contact array assembly in accordance with one embodiment of the present invention.

FIG. 33 is an exploded perspective view of a portion of the contact array assembly illustrated in FIG. 32.

FIG. 34 is a perspective view of a portion of the contact array assembly illustrated in FIG. 32.

FIG. 35 is a plan view of one of the contacts in the contact array assembly illustrated in FIG. 32.

FIG. 36 is a side view of the contact illustrated in FIG. 35.

FIG. 37 is an end view of the contact illustrated in FIG. 35.

FIG. 38 is a perspective view of the contact illustrated in FIG. 35.

FIG. 39 is a plan view of the contact array assembly illustrated in FIG. 35 on a wire bonding fixture.

FIG. 40 is a plan view of a portion of the contact array assembly illustrated in FIG. 32 on the wire bonding fixture illustrated in FIG. 39.

FIG. 41 is a perspective view of a portion of the contact array assembly illustrated in FIG. 32 on the wire bonding fixture illustrated in FIG. 39.

FIG. 42 is a plan, cutaway view of the contact array assembly illustrated in FIG. 32 in a mold with wires bonded thereto.

FIG. 43 is a section view taken along line 43-43 in FIG. 42.

FIG. 44 is a section view taken along line 44-44 in FIG. 42.

FIG. 45 is a section view taken along line 45-45 in FIG. 31.

FIG. 46 is a section view taken along line 46-46 in FIG. 31.

FIG. 47 is a perspective view of a portion of a cochlear lead in accordance with one embodiment of a present invention.

FIG. 48 is a section view taken along line 48-48 in FIG. 47.

FIG. 49 is a section view of a portion of a cochlear lead in accordance with one embodiment of a present invention.

FIG. 50 is a plan view of a contact array assembly in accordance with one embodiment of the present invention.

FIG. 51 is a side view of the contact array assembly illustrated in FIG. 50.

FIG. 52 is a section view taken along line 52-52 in FIG. 50.

FIG. 53 is a section view taken along line 53-53 in FIG. 50.

FIG. 54 is a plan view of a portion of an exemplary method of manufacturing the contact array assembly illustrated in FIG. 50 in accordance with one embodiment of a present invention.

FIG. 55 is a section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 56 is a partial section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 57 is a plan view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 58 is a section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 59 is a partial section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 60 is a plan view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 61 is an end view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 62 is a plan view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 63 is a plan view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 64 is a section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 65 is a section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 66 is a section view of a portion of the exemplary method of manufacturing the contact array assembly illustrated in FIG. 50.

FIG. 67 is a perspective view of a mold in accordance with one embodiment of a present invention.

FIG. 68 is a perspective view of a portion of the mold illustrated in FIG. 67.

FIG. 69 is a perspective view of a portion of the mold illustrated in FIG. 67.

FIG. 70 is a plan view of the contact array assembly illustrated in FIG. 50 on a portion of the mold illustrated in FIG. 67.

FIG. 71 is a section view of the contact array assembly illustrated in FIG. 50 within the mold illustrated in FIG. 67.

FIG. 72 is a section view of the contact array assembly illustrated in FIG. 50 within the mold illustrated in FIG. 67.

FIG. 73 is a side view of a contact array assembly in accordance with one embodiment of the present invention.

FIG. 74 is a section view of a portion of an exemplary method of manufacturing the contact array assembly illustrated in FIG. 73 in accordance with one embodiment of a present invention.

FIG. 75 is a section view taken along line 75-75 in FIG. 73.

FIG. 75A is a section view of a portion of an exemplary method of manufacturing a contact array assembly in accordance with one embodiment of a present invention.

FIG. 76 is a side view of a portion of cochlear lead in accordance with one embodiment of a present invention.

FIG. 77 is a perspective view of a contact array assembly in accordance with one embodiment of the present invention.

FIG. 78 is a perspective view of a portion of the contact array assembly illustrated in FIG. 77.

FIG. 79 is a side view of a portion of the contact array assembly illustrated in FIG. 77.

FIG. 80 is a side view of a portion of the contact array assembly illustrated in FIG. 77.

FIG. **81** is a perspective view of a portion of a contact array assembly in accordance with one embodiment of the present invention.

FIG. **82** is a perspective view of a portion of the contact array assembly illustrated in FIG. **81**.

FIG. **83** is a top view of a portion of the contact array assembly illustrated in FIG. **81**.

FIG. **84** is a perspective view of a mold in accordance with one embodiment of a present invention.

FIG. **85** is a plan view of the contact array assembly illustrated in FIG. **50** on a portion of the mold illustrated in FIG. **84**.

FIG. **86** is a plan view of a fixture in accordance with one embodiment of a present invention.

FIG. **87** is a side view the fixture illustrated in FIG. **86**.

FIG. **88** is a section view taken along line **88-88** in FIG. **87**.

FIG. **89** is a side view of a fixture in accordance with one embodiment of a present invention.

FIG. **90** is a side view of a fixture in accordance with one embodiment of a present invention.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The following is a detailed description of the best presently known modes of carrying out the inventions. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the inventions.

One example of a cochlear implant (or "implantable cochlear stimulator") in accordance with at least some of the present inventions is illustrated in FIGS. **1-7**. The cochlear implant **100** includes a flexible housing **102** formed from a silicone elastomer or other suitable material, a processor assembly **104**, a cochlear lead **106** with an electrode array **108**, and an antenna **110** that may be used to receive data and power by way of an external antenna that is associated with, for example, a sound processor unit. The electrode array **108** includes a flexible body **112** and a plurality of electrically conductive contacts **114** (e.g., the sixteen contacts **114** illustrated in FIG. **2**) spaced along the curved bottom surface **116** of the flexible body between the tip **118** and the base **120**. A positioning magnet **122** is located within a magnet pocket **124**. The magnet **122** is used to maintain the position of a headpiece transmitter over the antenna **110**. The cochlear implant may, in some instances, be configured is manner that facilitates magnet removal and replacement. Here, the housing **102** may be provided with a magnet aperture (not shown) that extends from the magnet pocket **124** to the exterior of the housing.

Suitable materials for the flexible body **112** include, but are not limited to, LSR, high temperature vulcanization ("HTV") silicone rubbers, room temperature vulcanization ("RTV") silicone rubbers, and thermoplastic elastomers ("TPEs"). The contacts **114** may be referred to in numbered order, 1^{st} through 16^{th}, with the contact closest to the tip **118** being the 1^{st} contact and the contact closest to the base **120** being the 16^{th} contact. The exemplary flexible body **112** also includes a longitudinally extending curved top surface **126** that does not include conductive contacts. Once implanted, the conductive contacts **114** on the curved surface **116** face the modiolus within the cochlea. The exemplary flexible body **112** has a circular shape in a cross-section perpendicular to the longitudinal axis LA of the electrode array **108** (FIGS. **4-7**). In other implementations, a truncated circular shape, with a flat top surface, or an oval shape, with or without truncation, or any other suitable shape, may be employed. It should also be noted that the methods of forming the electrode array described below produce smooth exterior surface transitions from the flexible body **112** to the contacts **114**.

Referring more specifically to FIG. **2**, in addition to the electrode array **108**, the exemplary cochlear lead **106** includes a wing **128**, with a rectangular portion **130** and a tapered portion **132**, which functions as a handle for the surgeon during the implantation surgery. The wing **128** also provides tension relief for lead wires **134** (FIG. **4**), which do not run straight through the wing. A tubular member **136**, which may consist of tubes of different sizes, extends from the wing **128** to the housing **102**. The contacts **114** are connected to the lead wires **134** that extend through the flexible body **112** and tubular member **136** to a connector (not shown) in the housing **102**.

The exemplary electrode array **108** has a tapered shape, with a diameter that is larger at the base **120** than at the tip **118**, and includes contacts **114** of different sizes and shapes. In the illustrated embodiment, there are three different contact configurations, i.e., contacts **114-1**, **114-2** and **114-3**, and reference numeral **114** is used herein to refer to all of the contacts generically. Contacts **114-1** (and the associated portion of the flexible body **112**) are larger than contacts **114-2** (and the associated portion of the flexible body), and contacts **114-2** (and the associated portion of the flexible body) are larger than contacts **114-3** (and the associated portion of the flexible body).

As illustrated in FIGS. **5** and **10-12**, the exemplary contacts **114-1** include a solid body **138**, a curved tissue contact surface **140**, side surfaces **142** with outer edges **144**, and a flat wire contact surface **146**. One or more apertures **148** (two cylindrical apertures in the illustrated implementation) extend through the solid body **138**. The apertures **148** are located inward of, and are offset from, the tissue contact surface **140**. Prior to the molding process, the apertures **148** support the contacts **114-1** on carrier rods **202**, as is discussed below with reference to FIGS. **8** and **9**. The carrier rods **202** are removed prior to the molding process used in the formation of the electrode array **108**. As a result, portions of the flexible body **112** are located within the apertures **148**, thereby interlocking the contacts **114-1** with the flexible body. As discussed below with reference to FIGS. **19-21**, one of the wires **134** is connected to the wire contact surface **146** at a bond **134'**. Turning to FIGS. **6** and **13-15**, the exemplary contacts **114-2** include a solid body **150**, a curved tissue contact surface **152**, and a flat wire contact surface **154** with outer edges **156**. One or more apertures **148** (two in the illustrated implementation) extend through the solid body **150**. The apertures **148** are located inward of, and are offset from, the tissue contact surface **152**. One of the wires **134** is connected to the wire contact surface **146** at a bond **134'**. The exemplary contacts **114-3** (FIGS. **7** and **16-18**) include a solid body **158**, a curved tissue contact surface **160**, side surfaces **162** with outer edges **164**, and a flat wire contact surface **166**. One or more apertures **148** (two in the illustrated implementation) extend through the solid body **158**. The apertures **148** are located inward of, and are offset from, the tissue contact surface **160**. One of the wires **134** is connected to the wire contact surface **166** at a bond **134'**.

Suitable conductive materials for the contacts **114** include, but are not limited to, platinum, platinum-iridium, gold and palladium. The exemplary contacts **114** may be solid (as shown) or a PEEK or ceramic structure that is coated or plated with the conductive material. With respect to dimensions, the exemplary contacts **114** are sized and shaped for insertion into the cochlea and have widths (measured horizontally in FIGS. **5-7**) that range from 0.35 mm to 0.5 mm, and radii that range from 0.17 mm to 0.25 mm. The exemplary apertures **148** are circular in cross-section with diameters that range from 0.1 mm to 0.15 mm. The distance between adjacent contacts **114** may range from 0.5 mm to 1.5 mm, and the distance may be constant or variable. It should also be noted that the contacts **114** have the same configuration before and after being placed onto the carrier rods **202** (discussed below).

Contacts such as contacts **114** may form part of a contact array assembly that is used during the formation of an electrode array. In the exemplary contact array assembly **200** illustrated in FIGS. **8** and **9**, which is used in the formation of the electrode array **108**, all three types of contacts **114** (i.e., contacts **114-1**, **114-2** and **114-3**) are positioned on carrier rods **202** that extend through the contact apertures **148**. The carrier rods **202** are located inward of, and are offset from, the tissue contact surfaces **140**, **152** and **160** of the contacts **114-1**, **114-2** and **114-3**. A slip fit, a line to line fit, or a slight friction fit between the contacts **114** and the carrier rods **202** allows the carrier rods to be separated from the contacts at the appropriate time (e.g., after the contact array assembly has been placed in a mold) without destroying the carrier rods and/or the contacts or altering the spacing between adjacent contacts. In some instances, instead of a slight friction fit, a small amount of medical grade adhesive may be used to fix the positions of the contacts **114** on the carrier rods **202** with bonds that are weak enough to allow the carrier rods to be separated from the contacts. Put another way, in the illustrated implementation, the carrier rods **202** are removably inserted into apertures **148** of the contacts **114**.

The exemplary carrier rods **202** are malleable, which allows the contact array assembly **200** to be bent in order to conform to curved molds that produce pre-curved electrode arrays. Suitable structures for the carrier rods **202** include, but are not limited to, stainless steel rods (e.g., gauge pins) with a diameter of 0.1 mm to 0.15 mm. In other implementations, the carrier rods may be resilient (i.e., will bend and then return to their original shape when the bending force is removed), super-elastic, or rigid. In other implementations, such as that described below with reference to FIGS. **28-30**, the carrier rods **202** may be formed from electrically non-conductive material such as PEEK, PTFE or polyester, as well as the shape memory materials described below.

It should also be noted here that the present contact array assemblies are not limited to the exemplary assembly **200**. For example, other implementations may include fewer than (or more than) sixteen contacts and/or contacts that all have the same configuration. Other exemplary contact array assemblies are described below with reference to FIGS. **31-75**.

As illustrated for example in FIGS. **19** and **20**, the contact array assembly **200** may be positioned on a wire bonding fixture **300** that holds the contact array assembly while the lead wires **134** are being bonded to the individual contacts **114**. The exemplary bonding fixture **300** includes a main body **302** and a channel **304** that is sized and shaped to accommodate the contacts **114**. Individual pockets (not shown) or other suitable structures may be provided within the channel **304** to insure that the electrodes **114** are properly spaced. After the contact array assembly **200** has been positioned on the wire bonding fixture **300**, each lead wire **134** (sixteen in the illustrated implementation) may be physically bonded and electrically connected to a respective one of the wire contact surfaces **146**, **154** and **166** of the contacts **114-1**, **114-2** and **114-3** in the manner illustrated in FIG. **21** (where only three lead wires are shown for purposes of clarity). For example, the end portion of each lead wire **134** may be stripped of insulation and bonded to the wire contact surface **146** (or **154** or **166**) by resistance welding, wire bonding, hot bar welding, or any other suitable technique to form the bonds **134'**. The bonds **134'** may be created in series, starting with contact sixteen (i.e., the contact **114-1** that will be closest to the base **120**) and ending with contact one (i.e. the contact **114-3** that will be closest to the tip **118**), to prevent damage to the lead wires **134**. The resulting lead wire bundle may be secured to the some or most of the contacts **114** with medical grade adhesive. The stiffness of the lead wires **134** helps maintain proper spacing between the contacts **114**.

The contact array assembly **200**, with wires **134** attached thereto, may thereafter be transferred to a mold into which the LSR (or other resilient material) will be injected to form the flexible body **112**. One example of such a mold is the mold **400** illustrated in FIGS. **22-27**. Referring first to FIGS. **22** and **23**, the exemplary mold **400** includes first and second mold parts **402** and **404**. The first mold part **402** includes a plate **406** with a contact surface **408** and an elongate cavity **410**. A resilient insert **412**, which includes a body **414**, a curved lead defining surface **416** and top ends **418** that extend beyond the contact surface **408** of the first mold part **402** (e.g., by 0.002 inch), may be positioned within the elongate cavity **410**. Suitable materials for the resilient insert include, but are not limited to, urethane, silicone, or any other suitable compliant material. The first mold part **402** and/or the resilient insert **412** may include verification indicia (not shown) so that, prior to molding, the spacing between the contacts **114** can be verified and, if necessary, adjusted. The second mold part **404** includes a plate **420** with a contact surface **422**, a curved lead defining surface **424** and edges **426** where the contact surface and channel intersect. After insertion of the contact array assembly **200**, and prior to injection of the LSR (or other resilient material), the first and second mold parts **402** and **404** may be clamped together with the lead defining surface **416** aligned with the lead defining surface **424**, which together define a mold cavity **428** the shape of the flexible body **112**. The top ends **418** are compressed to form a tight seal.

In the illustrated implementation, the mold parts **402** and **404** are intended to be reusable. Suitable materials for the mold plates **406** and **420** include, but are not limited to, stainless steel (e.g., **400** series stainless steel). The resilient insert **412** may be replaced as necessary. In other implementations, the mold may be a single-use device.

Turning to FIG. **24**, the contact array assembly **200**, with wires **134** attached thereto, may be pressed into the lead defining surface **416** of the resilient insert **412** while the first and second mold parts **402** and **404** are separated. The resilience of the insert **412** insures that there is a tight fit between the contacts **114** and the lead defining surface **416**. The masking effect of the tight fit prevents the LSR (or other resilient material) from flashing over the outer surfaces of the contacts **114** during the injection molding process. The first and second mold parts **402** and **404** may then be brought together and secured to one another, with the surfaces **408** and **422** (FIG. **23**) contacting one another and the mold part edges **426** engaging the edges **144**, **156** and **164** (FIGS. **5-7**) of the contacts **114-1**, **114-2** and **114-3** to press the tissue contact surfaces **140**, **152**, **160** against the lead defining surface **416**. The carrier rods **202** may then be pulled out of the contacts **114**, which leaves the apertures **148** open in the manner illustrated in FIGS. **25-27**. A clamp, screws or other suitable instrumentality (not shown) may be used to hold the mold parts **402** and **404** together. The tight fit between the contacts **114** and the lead defining surface **416** also prevents the contacts from moving when the carrier rods **202** are pulled out.

It should also be noted that the wing **128** (FIG. **2**) may in some instances be formed with a mold (not shown) which has a wing-shaped cavity and is aligned with the mold **400** during the injection process.

The LSR or other suitable resilient material may then be injected (or otherwise introduced) into the mold cavity **428**, both around the contacts **114** and into the apertures **148**, to form the flexible body **112**. The masking effect of the lead defining surface **416** prevents the resilient material from flashing over the outer surfaces of the contacts **114**. The resilient material within the apertures **148** (FIGS. **5-7**) creates a mechanical interlock between the flexible body **112** and the contacts **114**. After the resilient material hardens, the mold parts **402** and **404** may be separated from one another. The completed electrode array **108** may be removed from the insert **412** by, for example, simply pulling the completed flexible body **112** out of the insert.

There are some instances where it may be desirable to increase the stiffness of the electrode array in the region adjacent to the wing to, for example, prevent the electrode array from buckling during the insertion process. One example of a cochlear lead that includes such an increase in stiffness is the cochlear lead **106*a*** illustrated in FIGS. **28** and **29**. The cochlear lead **106*a*** is substantially similar to the cochlear lead **106** described above with reference to FIGS. **1-18**. For example, the cochlear lead **106*a*** includes an electrode array **108** with a flexible body **112** and a plurality of electrically conductive contacts **114** (e.g., the sixteen contacts **114** illustrated in FIG. **2**) between the tip and the base **120** that are connected to lead wires in the manner described above. A wing **128**, with a rectangular portion **130** and a tapered portion **132**, is located at the electrode array base **120**. The cochlear lead **106*a*** may also be incorporated into the cochlear implant **100** in place of the lead **106**.

Here, however, the lead **106*a*** also includes a stiffener **170** that extends through a plurality of the contacts **114**, through the base **120**, and into the wing **128**. The stiffener **170** has a first end **172** that is located within the rectangular portion **130** of the wing **128** and a second end **174** that is located within one of the contacts **114**.

In the illustrated implementation, the stiffener **170** is formed from portions **204** of the carrier rods **202** in the contact array assembly **200**. Instead of pulling the carrier rods **202** out of each of contacts **114-1**, **114-2** and **114-3** when the electrode array assembly is on the mold part **402**, as is described above with reference to FIGS. **24-27**, the carrier rods are pulled until they only remain in those contacts **114** through which the stiffener **170** is intended to extend. Referring to FIG. **30**, once the ends of the carrier rods **202** are aligned with only the intended contacts **114** (e.g., the four contacts **114-1** closest to the wing **128**), the carrier rods may be cut or otherwise severed along a cut line CL to form the rod portions **204** (FIG. **29**). The cut line CL may be located at the portion of the carrier rods **202** that will define the first end **172** of the stiffener **170**. The flexible body **112** may then be molded onto the contacts **114** in the manner described above. It should also be noted that the rods **202** use to form the stiffener **170** are electrically non-conductive.

It should also be noted that in those instances where portions of the carrier rods are used to form a stiffener that remains in a contact array assembly, one rod or more than two rods may be employed, and cross-sectional shapes other than circular may be employed to provide desired bending characteristics. By way of example, by not limitations, one or more carrier rods with oval, rectangular, octagon, I-beam, or other shapes may be employed.

Another exemplary cochlear lead that includes an increase in stiffness adjacent to the wing **128** is the cochlear lead **106*b*** illustrated in FIG. **31**. The cochlear lead **106*b*** is substantially similar to the cochlear lead **106*a*** described above with reference to FIGS. **28-30**. The cochlear lead **106*b***, which may also be incorporated into the cochlear implant **100** in place of the lead **106**, includes an electrode array **108*b*** with a flexible body **112*b*** and a plurality of electrically conductive contacts **114*b*** (e.g., the sixteen contacts **114*b*** illustrated in FIG. **32**) between the tip **118** and the base **120** that are connected to lead wires in the manner described below. Contact sixteen is closest to the base **120** and contact one is closest to the tip **118**. A wing **128**, with a rectangular portion **130** and a tapered portion **132**, is located at the electrode array base **120**. A stiffener **180** is associated with a plurality of the contacts **114*b*** that are adjacent to the base **120**. The stiffener **180** also extends into the wing **128**, and has a first end **182** that is located within the rectangular portion **130** of the wing **128** and a second end **184** that is located within the flexible body **120**. The stiffener **180** may be formed from portions of a contact array assembly **200*b*** (FIGS. **32-34**) that is used in the manufacturing process. In some instances, the end portion of the base **120** may include a reinforcement **114*b*'** which, in the illustrated implementation, is an electrically conductive contact that is identical to contacts **114*b*** and is not connected to a lead wire. Other types of reinforcements may also be provided.

Turning to FIGS. **32-34**, the exemplary contact array assembly **200*b*** includes the aforementioned plurality of electrically conductive contacts **114*b*** as well as a carrier **202*b*** that is defined by a plurality of relatively stiff, electrically non-conductive links **203*b***. As used herein, a relatively stiff link is a link that is formed from material that is stiffer than the LSR (or other resilient material) that is used to form the flexible body **112*b***. In the illustrated embodiment, there are three different link configurations, i.e., links **203*b*-1**, **203*b*-2** and **203*b*-3**, and reference numeral **203*b*** is used herein to refer to all of the links generically. The links **203*b*-1**, **203*b*-2** and **203*b*-3** include respective rods **206-1**, **206-2** and **206-3** as well as connectors **208** located at the longitudinal ends of the rods. The connectors **208** are configured to engage with, and disengage from, corresponding connectors **148*b*** on the contacts **114*b*** when the links **203*b*** are moved in the directions of arrows A and B (FIG. **33**). The connectors **208** will not, however, disengage from the corresponding connectors **148*b*** when the contacts **114*b*** are moved in the direction of arrow C. Some of the links **203*b*** will be removed from the assembly **200*b*** prior to the molding of the flexible body **112*b*** as is described below. The links **203*b*** are identical to one another but for the length of the rods **206-1**, **206-2** and **206-3** in the illustrated implementation, but may be different in other implementations. The length of the rods **206-1** corresponds to the distance between adjacent contacts **114*b***. The length of the rod **206-2**, which is greater than the length of the rods **206-1**, corresponds to the distance between the basal-most contact **114** and the reinforcement **114*b*'**. The length of the rod **206-3**, which is greater than the length of the rod **206-2**, corresponds to the distance that the stiffener **180** extends into the wing **128**.

The relatively stiff, electrically non-conductive links **203*b*** may be formed from material that is 1 to 1000% stiffer than the material used to form the flexible body **112**. Suitable materials for the links **203***b* include, but are not limited to high durometer LSR, PEEK, PTFE and polyester. Shape memory materials may also be employed. For example, the links may straight at room temperature (about 22 C) and curved at body temperature (about 37 C). Suitable shape memory materials include shape memory metals such as Nitinol (with an electrically non-conductive coating such as PTFE or parylene) and shape memory polymers such as polyethylene glycol (PEG). The shape memory links may be used to, for example, create an electrode array that conforms to the shape of the cochlea in a manner similar to a pre-curved electrode array. Such an electrode array provides certain advantages associated with pre-curved electrode arrays that are molded in a curved state, e.g., the ability to position some or all contacts closer to the modiolus, which can be useful in preventing cross-stimulation that occurs when two contacts stimulate the same part of modiolus, without sacrificing certain advantages associated with electrode arrays that are molded in a straight state, e.g., a relatively simple molding process.

The cross-sectional shape of the rods **206-1**, **206-2** and **206-3** may be rectangular, as shown. Other cross-sectional shapes, such as I-beam, circular, oval, or hexagon, may be employed to provide different bending characteristics. The connectors **208** are cylindrical, with a diameter larger than the width of the associated rod, in the illustrated implementation so as to correspond to the shape of the contact connectors **148***b*. Other shapes may also be employed.

Referring to FIGS. **35-38**, the exemplary electrically conductive contacts **114***b* include a solid body **138***b*, a curved tissue contact surface **140***b*, side surfaces **142***b* with outer edges **144***b*, and a wire contact surface **146***b*. The connectors **148***b* are located inward of, and are offset from, the tissue contact surface **140***b* (as shown). As a result, the links **203***b* are also located inward of, and are offset from, the tissue contact surface **140***b*. The connectors **148***b* also have configurations which correspond to those of the connectors **208**. To that end, the exemplary connectors **148***b* include a slot **150***b* having a relatively narrow portion **152***b* and a relatively wide portion **154***b*. The relatively narrow portion **152***b* has a rectangular shape while the relatively wide portion **154***b* has a circular shape. Other connector configurations that allow the contacts **114***b* and links **203***b* to be selectively connected and disconnected in the manner described above may be employed.

The respective configurations of the connectors **148***b* and **208** allow a portion of the carrier **202***b* (e.g., some of the links **203***b***-1**) to be separated from the contacts **114***b* at the appropriate time (e.g., after the contact array assembly has been placed in a mold) without destroying the links and/or the contacts or altering the spacing between adjacent contacts. Put another way, in the illustrated implementation, the links **203***b***-1** are removably secured to the contacts **114***b*.

The exemplary contacts **114***b* may also be provided with various features that facilitate connection to a lead wire in the manner described below with reference to FIGS. **40** and **41**. In the illustrated embodiment, the contacts **114***b* include a pair of slots **156***b* that extend from one longitudinal end to the other on opposite sides of the connectors **148***b* as well as a pair of indentations **158***b* between the slots and the wire contact surface **146***b*.

The exemplary contacts **114***b* may be formed from the conductive materials described above in the context of contacts **114**, i.e., materials such as platinum, platinum-iridium, gold and palladium. Suitable manufacturing processes include, but are not limited to, 3-dimensional photo-etching processes such as #D printing, selective laser sintering (SLS), LIGA lithography, electroplating and metal injection molding (MIM) processes. The size and spacing of the contacts **114***b* may be the same the contacts **114**. The contacts **114***b* may all be the same size (as shown) or may vary in size in those instances where the electrode array **108***b* has a tapered shape, with an array diameter that is larger at the base **120** than at the tip **118**.

As illustrated for example in FIG. **39**, the contact array assembly **200***b* may be positioned on a wire bonding fixture **300***b*, which holds the contact array assembly while the lead wires **134** are being bonded to the individual contacts **114***b*. The exemplary bonding fixture **300***b* includes a main body **302** and a channel **304***b* that is sized and shaped to accommodate the contacts **114***b*. Proper spacing of the contacts **114***b* is maintained by the carrier **202***b* and, in particular, by the links **203***b*. After the contact array assembly **200***b* has been positioned on the wire bonding fixture **300**, each lead wire **134** (sixteen in the illustrated implementation) may be physically bonded and electrically connected to a respective one of the wire contact surfaces **146***b* in the manner illustrated in FIGS. **40** and **41**. For example, the end portion of each lead wire **134** may be stripped of insulation and fed through one of the slots **156***b* of a contact **114***b* and then redirected onto the wire contact surface **146***b*. The end portion of each lead wire **134** may then be bonded to the wire contact surface **146***b* by resistance welding, wire bonding, hot bar welding, or any other suitable technique to form the bonds **134'**. The bonds **134'** may be created in series, starting with contact sixteen (i.e., the contact **114***b* that will be closest to the base **120**) and ending with contact one (i.e. the contact **114***b* that will be closest to the tip **118**), to prevent damage to the lead wires **134**. In some instances, the choice of slot **156***b* may alternate from one contact **114***b* to the next and, accordingly, eight lead wires **134** will extend towards and past the reinforcement **114***b*' on one side of the links **203***b* and another eight lead wires will extend towards and past the reinforcement on the other side of the links.

The contact array assembly **200***b*, with wires **134** attached thereto, may thereafter be transferred to a mold into which the LSR (or other resilient material) will be injected to form the flexible body **112***b*. One example of such a mold is the mold **400***b* illustrated in FIGS. **42-44**. The mold **400***b* is substantially similar to mold **400** and similar elements are represented by similar reference numerals. For example, the mold **400***b* includes first and second mold parts **402** and **404**. The first mold part **402** includes a plate **406** with a contact surface **408**, an elongate cavity **410**, and a resilient insert **412***b* with a lead defining surface **416***b* that is configured to accommodate the contacts **114***b*. The second mold part **404** includes a plate **420** with a contact surface **422** and a curved lead defining surface **424***b*. The first and second mold parts **402** and **404** may be clamped together with the lead defining surface **416***b* aligned with the lead defining surface **424***b*, which together define a mold cavity **428***b* the shape of the flexible body **112***b*.

During the molding process, the contact array assembly **200***b*, with wires **134** attached thereto, may be pressed into the lead defining surface **416***b* of the resilient insert **412***b* while the first and second mold parts **402** and **404** are separated, as is discussed in greater detail above in the context of mold **400**. The links **203***b* will maintain the proper spacing between the contacts **114***b*, as well as between the basal-most contact **114***b* and the reinforcement **114***b*'. A portion of the carrier **202***b* (i.e., some of the links **203***b***-1**) that will not form part of the stiffener **180** may then be removed (FIG. **42**) by simply moving the links in the direction of arrow B (FIG. **33**), while the links that will form part of the stiffener **180** will remain attached to the associated contacts **114***b*. The lead wires **134** may then be bundled in, for example, the manner illustrated in FIG. **43**. The first and second mold parts **402** and **404** may then be brought together and secured to one another, and the LSR or other suitable resilient material may then be injected (or otherwise introduced) into the mold cavity **428***b* to form the flexible body **112***b*, as shown in FIGS. **45** and **46**. After the resilient material hardens, the mold parts **402** and **404** may be separated from one another. The completed electrode array **108***b* may be removed from the insert **412***b* by, for example, simply pulling the completed flexible body **112***b* out of the insert.

There are some instances where it may be desirable to pre-curve the cochlear lead. One example of a cochlear lead that includes a pre-set curvature is the cochlear lead **106***c* illustrated in FIG. **47**. The cochlear lead **106***c* is substantially similar to the cochlear lead **106** described above with reference to FIGS. **1-18**. For example, the cochlear lead **106***c* includes an electrode array **108***c* with a curved flexible body **112***c* and a plurality of electrically conductive contacts **114***c* (e.g., sixteen contacts) between the tip **118** and the base **120** that are connected to lead wires **134**. A wing **128***c*, with a cylindrical portion **130***c* and a tapered portion **132***c*, is located at the electrode array base **120**. A marker contact **114***c*', which is not connected to a lead wire, is located adjacent to the base **120**. The cochlear lead **106***c* may also be incorporated into the cochlear implant **100** in place of the lead **106**.

The exemplary electrode array **108***c* has a circular cross-section and the curved tissue contact surfaces **140***c* of the contacts **114***c* extend about one-half of the way around (i.e., about 180 degrees around) the perimeter of the array. The contacts may, however, have tissue contact surfaces that extend more or less than one-half of the way around the perimeter in other implementations. For example, the electrode array **108***cc* illustrated in FIG. **49** is otherwise identical to electrode array **108***c* and includes a plurality of contacts **114***d* on a curved flexible body **112***d*. The contacts **114***d* have curved tissue contact surfaces **140***d* that extend more than one-half of the way around (i.e., more than 180 degrees around) the perimeter of the cross-section.

Contacts such as contacts **114***c* and marker **114***c*' may form part of a contact array assembly that is used during the formation of the exemplary electrode array **108***c*. The contacts **114***c* and marker **114***c*' in the exemplary contact array assembly **200***c* illustrated in FIGS. **50-53** are positioned on a carrier **202***c*. The contact array assembly **200***c* also includes the lead wires **134**. The carrier **202***c* may be formed from the same material as, and ultimately becomes part of, the flexible body **112***c*. To that end, the carrier **202***c* includes a curved bottom surface **210***c*, which will become part of the curved bottom surface **116***c* of the flexible body **112***c*, and a top surface **212***c*. The lead wires **134** are secured to the remainder of the contact array assembly **200***c* in such a manner that the lead wires are less likely to break, as compared to conventional assemblies, when the contact array assembly **200***c* is inserted into a curved mold. In particular, each of the lead wires **134** may be secured only to the associated contact **114***c* and positioned on top of the carrier top surface **212***c* (as opposed to molding the lead wires into the carrier **202***c*). As a result, when the straight contact array assembly **200***c* is pressed into a curved mold in, for example, the manner described below with reference to FIGS. **70-72**, the lead wires **134** will be free to move relative to the carrier **202***c* and will be less likely to break due to tension.

The exemplary contact array assembly **200***c* may be formed in the exemplary fixture **300***c* illustrated in FIG. **54** in accordance with the method described below with reference to FIGS. **55-62**. The fixture **300***c* includes a plate **302***c* with a top surface **304***c* and an elongate cavity **306***c* with a curvature corresponding to that of the electrode array **108***c*. The top surface **304***c* includes markers **308***c* which correspond to the intended locations of the contacts **114***c*. Here, there is a single marker **308***c* for each of the contacts **114***c*. In another implementation (not shown), a set of four markers **308***c* (two on each side of the cavity **306***c*) may be provided for each of the contacts **114***c*. A wire rest **310***c* extends upwardly from the top surface **304***c*.

The fixture **300***c* may in some instances be a disposable part formed by a photoetching process. Although iron and other photoetchable materials may be employed, the fixture **300***c* is formed from copper, which is relatively inexpensive and has a number of advantageous properties. Copper is unlikely to bond to platinum contacts **114***c* because copper does not weld easily and has relatively high thermal conductivity, which causes heat to dissipate very readily. Copper is also resilient in that it will flex slightly and return to its shape when the platinum contact workpieces (discussed below) are pressed through the opening. Copper is easy to bend, which facilitates release of the electrode array (discussed below). Also, as copper is electrically conductive, it may be used in an opposed weld process where the copper fixture **300***c* forms part of the electrical loop. In other implementations, the fixture **300***c* may be a reusable apparatus that consists of two separable pieces formed from a harder material such as stainless steel.

The exemplary method involves placing contact workpieces **312***c* into the cavity **306***c* at locations corresponding to the contacts **114***c* and marker **114***c*', as well as placing one end of a lead wire **134** into each workpiece in the case of the contacts **114***c*, and then applying heat and pressure to the workpiece. Referring first to FIGS. **54** and **55**, the exemplary contact workpiece **312***c* is a tube defined by a wall **314***c* formed from platinum or other suitable contact material. Although not limited to any particular shape, the exemplary workpiece is a cylindrical tube and is circular in cross-section. The workpiece **312***c* illustrated in FIGS. **54** and **55** will form the marker **114***c*'. The heat and pressure causes compression and distortion of the malleable workpiece **312***c* as shown in FIG. **56**. Portions of the wall **314***c* will come into contact with one another along a seam **318***c*. In some instances, gaps (not shown) may remain between some portions of the wall. The gaps augment the mechanical interconnection between the carrier **202***c* and the contacts **114***c*.

The heat and pressure may be applied with, for example, a weld tip, such as the molybdenum weld tip **316***c*, in a resistance welding process. In other implementations, the marker **114***c*' and contacts **114** may be formed by compressing the workpiece **312***c* with a stainless steel weld tip (no heat applied) and then applying heat with a molybdenum weld tip, thereby preventing wear on both weld tips.

Turning to FIGS. **57** and **58**, formation of the contact **114***c* closest to the marker **114***c*' (as well as the other contacts) involves placing a workpiece **312***c* into the cavity **306***c* and placing the end of the lead wire **134** into the workpiece. Heat and pressure may then be applied to the workpiece **312***c* to form the contact **114***c*, and bond the end of the lead wire **134** to the contact, in the manner illustrated in FIG. **59**. It should also be noted that the marker **114***c*' and contact **114** are pressed tightly against the mold surface **320***c* that defines the cavity **306***c*, thereby preventing movement of the marker and contact and also masking the curved tissue contact surfaces **140***c* of the marker and contact. The mold surface **320***c* also defines a portion of the outer surface of carrier **202***c* in the spaces not covered by the contacts **114***c*.

Turning to FIGS. **60** and **61**, one end of the associated lead wire **134** will be secured to the associated contact **114***c*, and therefore immovable relative to the contact, after the contact is formed. The remainder of the lead wire **134** may be moved out of the cavity **306***c*. As a result, the portion of the lead wire **134** that is coextensive with the carrier **202***c* will not be molded into carrier. In the illustrated implementation, the lead wire **134** may be directed over the wire rest **310***c*.

The steps described above with reference to FIGS. **57-61** may then be repeated to form the remainder to the contacts **114***c*. Referring to FIGS. **62** and **63**, after each contact **114***c* is formed by compressing workpiece **312***c* onto the end of the associated lead wire **134**, the lead wires may be may be directed out of the cavity and over the wire rest **310***c*.

Once all of the contacts **114***c* have been formed, and while the lead wires **134** remain outside of the cavity **306***c*, LSR or other suitable resilient material may then be injected (or otherwise introduced) into the cavity **306***c* as shown in FIG. **64** to form the carrier **202***c*. After the resilient material has cured to such an extent that the lead wires **134** will not sink into it, the lead wires may be positioned on the top surface **212***c* (FIG. **65**) to complete the contact array assembly **200***c*. The contact array assembly **200***c* may be removed from the fixture **300***c* by simply pulling the assembly out of the cavity **306***c*. Referring to FIG. **66**, bending of the plate **302***c* may be required in some instances when removing the contact array assembly **200***c* from the cavity **306***c*.

The contact array assembly **200***c* may then be placed into a mold to form the remainder of the curved cochlear lead **106***c*. Referring to FIGS. **67-70**, one example of such a mold is the mold **400***c* with mold parts **402***c*-**406***c*. The mold part **402***c* includes a block **408***c* with straight and curved portions **410***c* and **412***c*. A semi-circular lead defining surface **414***c*, with straight and curved portions **416***c* and **418***c*, is formed in the straight and curved portions **410***c* and **412***c* of the block **408***c*. A semi-circular surface **420***c* with a shape corresponding to a portion of the wing **128***c* is also formed in the straight portion **410***c*. In some instances, a resilient insert (not shown) similar to the insert **412** described above with reference to FIGS. **22-27** may be provided. The mold parts **404***c* and **406***c* respectively include blocks **422***c* and **424***c* with semi-circular lead defining surfaces **426***c* and **427***c* (FIGS. **71** and **72**) which, together with the lead defining surface **414***c*, define the mold cavity **428***c* (FIGS. **71** and **72**) that is used to form the flexible body **112***c*. The mold part **404***c* also includes a semi-circular surface (not shown) with a shape corresponding to a portion of the wing **128***c*.

After insertion of the contact array assembly **200***c*, and prior to injection of the LSR (or other resilient material), the mold parts **402***c*-**406***c* may be clamped together with the lead defining surfaces **414***c*, **426***c* and **427***c* aligned in the manner described above to define a mold cavity **428***c* the shape of the flexible body **112***c*. The LSR or other suitable resilient material may then be injected (or otherwise introduced) into the mold cavity **428***c* to form the flexible body **112***c*. After the resilient material hardens, the mold parts **402***c*-**406***c* may be separated from one another and the completed electrode array **108***c* may be removed.

Some cochlear leads with pre-set curvatures are straightened prior to the insertion process by a stylet or other stiffening element that is inserted into a stylet lumen within the electrode array. The present contact array assemblies may be configured to provide such a stylet lumen. To that end, and referring for example to FIG. **73**, the exemplary contact array assembly **200***d* is substantially similar to contact array assembly **200***c* and similar elements are identified by similar reference numerals. For example, the contact array assembly **200***d* includes the contacts **114***c* and marker **114***c*', carrier **202***c* (with bottom and top surfaces **210***c* and **212***c*), and the lead wires **134**. Here, however, the contact array assembly **200***d* also includes a hollow tube **214***d*. The tube **214***d* may be added to the remainder of the contact array assembly **200***d* either before or after the contact array assembly is placed into a mold (e.g., mold **400***c* in FIG. **67**). Suitable materials for the tube **214***d* include, but are not limited to, silicone elastomers such as Silastic® silicone elastomer from Dow Corning.

Referring to FIG. **74**, in those instances where the tube **214***d* is added to the remainder of the contact array assembly **200***d* prior to placement into the mold, the tube may be positioned on (and pressed slightly into) the LSR or other resilient material which forms the carrier **202***c* prior to the material hardening and prior to the lead wires **134** be positioned over the top surface **212***c*. The lead wires **134** may then be positioned on and over the tube **214***d* and the carrier **202***c*, as is shown in FIG. **75**. Turning to FIG. **75**A, in those instances where the tube **214***d* is added after the other portions of the contact array assembly have been placed onto a portion of curved mold (such as the mold part **402***c*), the tube may be bent around the carrier **202***c* and placed over the lead wires **134**. Small spaced quantities **203** of the LSR or other resilient material that forms the carrier **202***c* may be applied to hold the tube **214***c* in place and complete the contact array assembly **200***d*'. The molding process may then proceed in the manner described above.

There are some instances where it may be desirable to pre-curve a cochlear lead that includes a stiffener. One example of a cochlear lead that includes a pre-set curvature and a stiffener is the cochlear lead **106***d* illustrated in FIG. **76**. The cochlear lead **106***d* includes various aspects of the above-described cochlear leads **106***b* and **106***c* and similar elements are represented by similar reference numerals. For example, the cochlear lead **106***d* includes an electrode array **108***d* with a curved flexible body **112***d* and a plurality of electrically conductive contacts **114***b* (e.g., sixteen contacts) on the curved bottom surface **116***d* between the tip **118** and the base **120**. The contacts **114***b* are connected to lead wires in the manner described above. A wing **128**, with a rectangular portion **130** and a tapered portion **132**, is located at the electrode array base **120**. The end portion of the base **120** may include a reinforcement **114***b*' which, as noted above, is a contact **114***b* that is not connected to a lead wire. The cochlear lead **106***d* may also be incorporated into the cochlear implant **100** in place of the lead **106**.

The exemplary cochlear lead **106***d* also includes a stiffener **180***d* having first and second stiffener portions **180***d*-**1** and **180***d*-**2**. The first stiffener portion **180***d*-**1** may be associated with the four active contacts **114***b* closest to the base **120** (i.e., contacts thirteen to sixteen) as well as the reinforcement **114***b*', and may also extend into the wing **128**. The second stiffener portion **180***d*-**2** may be associated with a common contact **114***b* that is also associated with the first stiffener portion **180***d*-**1** as well as an additional six contacts (i.e., contacts thirteen to seven). The first stiffener portion **180***d*-**1** may be identical to the stiffener **180** described above with reference to FIGS. **31-46**, while the second stiffener portion **180***d*-**2** is configured to both provide axial stiffness and to accommodate the curvature of the curved portion of the flexible body **112***d*, bending of the electrode array **108***d* that occurs during insertion into the cochlea, and placement of the associated contact array assembly into a curved mold in a manner similar to the mold described above with reference to FIGS. **67-70**.

The exemplary stiffener **180***d*, which has ends **182** and **184**, may be formed from portions of a contact array assembly that is used in the manufacturing process. Referring to FIGS. **77-80**, the exemplary contact array assembly **200***e* is substantially similar to contact array assembly **200***b* (FIGS. **32-41**) and similar elements are represented by similar reference numerals. For example, the exemplary contact array assembly **200***e* includes the aforementioned plurality of electrically conductive contacts **114***b* as well as a carrier **202***e* that includes plurality of relatively stiff, electrically non-conductive links. In particular, the carrier **202***e* includes a link **203***b*-**1** and a link **203***b*-**2** (see FIG. **32**) as well as a plurality of links **203***b*-**3**, all of which are described above. There are three links **203***b*-**3**, which connect contacts thirteen through sixteen, in the illustrated sixteen contact implementation. The carrier **202***e* also includes a plurality of jointed links **203***e*. The jointed links **203***e* form the remainder of the links in the contact array assembly **200***e*, and connect contacts one through thirteen. Each jointed link **203***e* is configured to allow at least one portion of the link to pivot relative to another portion. As is discussed in greater detail below, the links **203***b*-**1** to **203***b*-**3** will form the first stiffener portion **180***d*-**1**, while at least some of the jointed links **203***e* will form the second stiffener portion **180***d*-**2**. Other jointed links **203***e* may be removed prior to the formation of the flexible body.

The exemplary links **203***e*, which may be formed from the same material as the links **203***b*, each include first and second rods **206***e*-**1** and **206***e*-**2** that are connected to one another by a joint **207***e*. One end of each of the rods **206***e*-**1** and **206***e*-**2** includes a connector **208**. The connectors **208** are configured to engage with, and disengage from, corresponding connectors **148***b* on the contacts **114***b* in the manner described above. The other ends of the rods **206***e*-**1** and **206***e*-**2** respectively include joint members **209***e*-**1** and **209***e*-**2** (FIGS. **78-80**). Although the present joints are not limited to any particular configuration, the joint members **209***e*-**1** and **209***e*-**2** in the illustrated embodiment are C-shaped and cylindrical, respectively, and allow the first and second rods **206***e*-**1** and **206***e*-**2** to pivot relative to one another about an axis A from, for example, the rod positions illustrated in FIGS. **78-79** to, for example, the rod positions illustrated in FIG. **80**.

With respect to the formation of the cochlear lead **106***d*, the contact array assembly **200***e* may be placed into a wire bonding fixture, such as the wire boding fixture **300***b* (FIG. **39**), and the lead wires may then be bonded to the individual contacts **114***b* in the manner described above with reference to FIGS. **39-41**. The contact array assembly **200***e*, with lead wires attached thereto, may thereafter be transferred onto the appropriate mold part of a curved mold. The curved mold may be similar to the mold **400***c* (FIGS. **67-70**). The links **203***b*-**1** to **203***b*-**3** will be on the straight portion of the mold, while the jointed links **203***e* will be on the curved portion of the mold and, in at least some instances, also on the straight portion. The links **203***b*-**1** to **203***b*-**3** will remain in place to form the first stiffener portion **108***d*-**1**. Some of the jointed links **203***e* may be removed (e.g., the jointed links between contacts one to seven) prior to the closing the mold, and the remaining jointed links will form the second stiffener portion **108***d*-**2**. After the mold parts have been clamped together in the manner described above to define a mold cavity in the shape of the flexible body **112***d*, the LSR or other suitable resilient material may be injected (or otherwise introduced) into the mold cavity to form the flexible body. After the resilient material hardens, the mold parts may be separated from one another and the completed electrode array **108***d* may be removed.

In other implementations, contact array assemblies may be provided with jointed links that pivot in other directions. By way of example, but not limitation, the exemplary contact array assembly **200***f* illustrated in FIG. **81** is identical to the contact array assembly **200***e* but for the use of jointed links **203***f* in the carrier **202***f* in place of jointed links **203***e*. Here too, the exemplary links **203***f* each include first and second rods **206***f*-**1** and **206***f*-**2** that are connected to one another by a joint **207***f*. One end of each of the rods **206***f*-**1** and **206***f*-**2** includes a connector **208**. The other ends of the rods **206***f*-**1** and **206***f*-**2** respectively include joint members **209***f*-**1** and **209***f*-**2**. Although the present joints are not limited to any particular configuration, the joint members **209***f*-**1** and **209***f*-**2** in the illustrated embodiment are cylindrical and C-shaped, respectively, and allow the first and second rods **206***f*-**1** and **206***e*-**2** to pivot relative to one another about an axis **A1** from, for example, the rod positions illustrated in FIGS. **81-82** to, for example, the rod positions illustrated in FIG. **83**. The axis **A1** is offset from axis A (FIG. **78**) by 90 degrees. One exemplary use of the contact array assembly **200***f* is the formation of an electrode array of the type described below with reference to FIG. **84**.

In still other implementations, the jointed links may be ball and socket joints, or simply weak points formed in the rods **206-1** of the links **203***b*-**1** (FIGS. **32** and **34**), to facilitate movement in multiple directions. Alternatively, or in addition, all of the links in some contact array assemblies may be jointed.

It should also be noted here that the present cochlear leads with pre-set curvatures are not limited to curves that define a flat plane. By way of example, the present cochlear leads include cochlear leads with pre-set generally helical shape. One example of a mold that may be used to produce such is the mold **400***d* illustrated in FIGS. **84** and **85**. The mold **400***d* is similar to mold **400***c* and similar elements are represented by similar reference numerals. To that end, the mold **400***d* includes mold parts **402***d*-**406***d*. The mold part **402***d* includes a block **408***d* with straight and curved portions **410***d* and **412***d*. A semi-circular lead defining surface **414***d*, with straight and curved portions **416***d* and **418***d*, is formed in the straight and curved portions **410***d* and **412***d* of the block **408***d*. Unlike the mold **400***c*, however, the lead defining surface **414***d* includes at least one bend point **415***d* where the lead defining surface is redirected by an angle Θ. The lead defining surface portion **418***d* will, therefore, extend helically around the curved portion **412***d* of the block **408***d*. A semi-circular surface **420***d* with a shape corresponding to a portion of the wing **128** is also formed in the straight portion **410***d*. In some instances, a resilient insert (not shown) similar to the insert **412** described above with reference to FIGS. **22-27** may be provided. The mold parts **404***d* and **406***d* respectively include blocks **422***c* and **424***c* with semi-circular lead defining surfaces (not shown) which are coextensive with the lead defining surface **414***d* and, together with the lead defining surface **414***d*, define the mold cavity that is used to form a flexible body with a helical portion. The mold part **404***d* also includes a semi-circular surface (not shown) with a shape corresponding to a portion of the wing.

One example of a contact array assembly that may be inserted into the mold **400***d* and used to form a cochlear lead with pre-set generally helical shape is the contact array assembly **200***d*, as shown. Contact array assemblies with various combinations of the links **203***b*, the link **203***e* and/or the link **203***f* may also be employed.

As described in greater detail above, manufacture of the present contact array assemblies involves positioning the ends of a plurality of lead wires adjacent to the associated electrically conductive contacts or the workpieces that are used to form the contacts. The efficiency of this aspect of the manufacturing process may be improved through the use of wire holders that position the ends of the lead wires adjacent to the associated contacts or workpieces in such a manner that the ends of the lead wires may be readily pulled from the holder and positioned at the intended location.

One example of a fixture with such a wire holder is the exemplary fixture **300***d* illustrated in FIGS. **86**-**88**. The fixture **300***d* is substantially similar to fixture **300***c* and similar elements are represented by similar reference numerals. For example, the fixture **300***d* includes the aforementioned plate **302***c* with a top surface **304***c*, an elongate cavity **306***c*, and a plurality of markers **308***c*. Here, however, the wire rest **310***c* has been omitted and replaced by a wire holder **310***d*. The exemplary wire holder **310***d*, which includes a tubular member **322***d* and a horizontal slot **324***d* that extends through the tubular member, may be secured to the top surface **304***c* of the plate **302***c* or simply held in place by the technician. Although not so limited, suitable materials for the tubular member **322***d* include silicone elastomers such as Silastic® silicone elastomer from Dow Corning.

The lead wires **134** may be positioned with the tubular member **322***d* in such a manner that the ends extend through the slot **324***d* at locations corresponding to the contacts. Such an arrangement allows portions of the lead wires **134** to be pulled through the slot **323***d* as needed (e.g., just prior to the compression of a workpiece). The remainders of the lead wires **134** may continue to be held by the holder **310***d* until all of the wires have been connected to contacts. In those instances where a carrier is to be formed (e.g., a carrier **202***c*), the holder **310***d* may be used to keep the wires out of the cavity **306***c* while resilient material is injected into the cavity in a manner similar to that described above in the context of the wire rest **310***c* and the contact array assembly **202***c*. The remainder of the lead wires **134** may then be pulled through the slot **324***d* and the holder **310***d* discarded or reused.

Another exemplary fixture with a wire holder is the fixture **300***e* with a wire holder **310***e* illustrated in FIG. **89**. The wire holder **310***e* includes a tubular member **322***e* with a horizontal slot **324***e* that extends through the tubular member. Vertical slots **324***e*, which facilitate accurate placement of the wire ends relative to the plate **302***c*, as well as relative to the contacts or workpieces on the plate, also extend through the tubular member **322***e*. Turning to FIG. **90**, the exemplary fixture **300***f* includes a wire holder **310***f* with a tubular member **322***f* and a plurality of spaced apertures **324***e* through which the respective plurality of lead wire ends extend. The tubular member **322***f*, with the lead wires extending therethrough, may form part of the associated electrode array.

Although the inventions disclosed herein have been described in terms of the preferred embodiments above, numerous modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art. By way of example, but not limitation, the inventions include any combination of the elements from the various species and embodiments disclosed in the specification that are not already described. It is intended that the scope of the present inventions extend to all such modifications and/or additions and that the scope of the present inventions is limited solely by the claims set forth below.

We claim:

1. A method of forming a cochlear implant electrode array, comprising the steps of:

positioning a contact array assembly, which includes at least one carrier and a plurality of electrically conductive contacts on the at least one carrier prior to being positioned in a mold, in the mold;

removing at least a portion of the at least one carrier from the mold without removing the plurality of electrically conductive contacts from the mold; and

introducing resilient material into the mold after the at least a portion of the at least one carrier has been removed from the mold to form a flexible body.

2. A method as claimed in claim **1**, wherein

the at least one carrier comprises at least one carrier rod.

3. A method as claimed in claim **2**, wherein

the at least one carrier rod comprises a plurality of carrier rods.

4. A method as claimed in claim **2**, wherein

the at least one carrier rod is malleable or resilient.

5. A method as claimed in claim **2**, wherein

the at least one carrier rod is rigid.

6. A method as claimed in claim **2**, wherein

the electrically conductive contacts have at least one contact aperture that is offset from the tissue contact surface; and

the at least one carrier rod extends through the at least one contact aperture of each electrically conductive contact.

7. A method as claimed in claim **6**, wherein

the at least one contact aperture comprises at least one cylindrical contact aperture.

8. A method as claimed in claim **6**, wherein

the step of introducing resilient material comprises injecting resilient material into the mold and the at least one contact aperture of each electrically conductive contact to form the flexible body.

9. A method as claimed in claim **2**, wherein

the step of removing at least a portion of the at least one carrier comprises removing the entire at least one carrier rod from the mold without removing the plurality of electrically conductive contacts from the mold.

10. A method as claimed in claim **1**, wherein

the at least one carrier comprises a plurality of relatively stiff, electrically non-conductive links.

11. A method as claimed in claim **10**, wherein

at least one of the relatively stiff, electrically non-conductive links includes first and second rods that are connected to one another by a joint that allows the rods to move relative to one another.

12. A method as claimed in claim **10**, wherein

at least some of the electrically conductive contacts define longitudinal ends and include a wire contact surface, a pair of slots that extend from one longitudinal end to the other on opposite sides of the wire contact surface, and a pair of indentations between the slots and the wire contact surface.

13. A method as claimed in claim **1**, further comprising the step of:

connecting lead wires to the electrically conductive contacts prior to positioning the contact array assembly in the mold.

14. A method as claimed in any claim **1**, wherein

at least two of the electrically conductive contacts have different sizes and/or shapes.

15. A method as claimed in claim **1**, wherein

the electrically conductive contacts include a curved tissue contact surface and a flat wire contact surface.

16. A method as claimed in claim **1**, wherein

the electrically conductive contacts defines widths that are within the range of 0.35 mm to 0.5 mm.

17. A method as claimed in claim **1**, wherein

the mold includes a resilient portion with curved lead defining surface; and

the electrically conductive contacts are pressed against the resilient portion when the contact array assembly is positioned within the mold.

18. A method of forming a cochlear implant electrode array, comprising the steps of:

positioning a contact array assembly, which includes at least one carrier rod and a plurality of electrically conductive contacts on the at least one carrier rod, in a mold;

removing less than the entire at least one carrier rod from the mold, such that at least one electrically conductive contact remains on the at least one carrier rod, without removing the plurality of electrically conductive contacts from the mold; and

introducing resilient material into the mold after the at least a portion of the at least one carrier rod has been removed from the mold to form a flexible body.

19. A method as claimed in claim **18**, wherein

the at least one carrier rod defines an exterior surface; and

at least the exterior surface of the at least one carrier rod is electrically non-conductive.

20. A method of forming a cochlear implant electrode array, comprising the steps of:

positioning a contact array assembly, which includes at least one carrier and a plurality of electrically conductive contacts on the at least one carrier, in a mold;

removing at least a portion of the at least one carrier from the mold without removing the plurality of electrically conductive contacts from the mold; and

introducing resilient material into the mold after the at least a portion of the at least one carrier has been removed from the mold to form a flexible body;

wherein

the at least one carrier comprises a plurality of relatively stiff, electrically non-conductive links;

the electrically conductive contacts include contact connectors;

the links include link connectors; and

the contact connectors and the link connectors are respectively configured such that the link connectors can engage with, and disengage from, the contact connectors.

21. A method of forming a cochlear implant electrode array, comprising the steps of:

positioning a contact array assembly, which includes a plurality of relatively stiff, electrically non-conductive links and a plurality of electrically conductive contacts on the links, in a mold;

removing fewer than all of the links from the mold, such that at least one electrically conductive contact remains connected to at least one link, without removing the plurality of electrically conductive contacts from the mold; and

introducing resilient material into the mold after fewer than all of the links have been removed from the mold to form a flexible body.

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